

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

COUNTY OF HARRIS, TEXAS

Plaintiff,

v.

ELI LILLY AND COMPANY; NOVO
NORDISK INC.; SANOFI-AVENTIS U.S.
LLC; EXPRESS SCRIPTS HOLDING
COMPANY; EXPRESS SCRIPTS, INC.;
ESI MAIL PHARMACY SERVICES, INC.;
EXPRESS SCRIPTS PHARMACY, INC.;
CVS HEALTH CORPORATION;
CAREMARK RX, L.L.C.; CAREMARK PCS
HEALTH, L.L.C.; CAREMARK, L.L.C.;
CAREMARK TEXAS MAIL PHARMACY,
LLC; OPTUM, INC.; OPTUMRX INC.;
AETNA RX HOME DELIVERY, LLC AND
AETNA PHARMACY MANAGEMENT
SERVICES, LLC.

Defendants.

Case No. 4:19-cv-04994

Jury Trial Demanded

PLAINTIFF'S SECOND AMENDED COMPLAINT

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Plaintiff, Harris County, Texas, by and through the undersigned attorneys (“Plaintiff” or “Harris County”) brings this lawsuit against Defendants: Eli Lilly and Company; Novo Nordisk Inc.; Sanofi-Aventis U.S. LLC; Express Scripts Holding Company; Express Scripts, Inc.; ESI Mail Pharmacy Service, Inc.; Express Scripts Pharmacy, Inc.; CVS Health Corporation; Caremark Rx, L.L.C.; Caremark PCS Health, L.L.C.; Caremark, L.L.C.; Caremark Texas Mail Pharmacy, LLC; Optum, Inc.; OptumRx Inc.; Aetna Rx Home Delivery, LLC and Aetna Pharmacy Management Services, LLC (collectively, “Defendants”). Plaintiff alleges on information and belief as follows:

I. INTRODUCTION

1. Diabetes is an epidemic in the United States. The total estimated cost of diagnosed diabetes in 2017 was \$327 billion, including \$237 billion in direct medical costs and \$90 billion in reduced productivity.¹ In Houston, Texas alone, diabetes-related costs reached \$4.1 billion in 2015.² One in four health care dollars is spent caring for people with diabetes.³ In total, nearly thirty (30) million people, 9.3% of the country, live with this disease.⁴ Of this number, approximately six million people rely on daily insulin treatments to survive.⁵

¹ See American Diabetes Association, *The Staggering Cost of Diabetes*, March 2018, available at <https://www.diabetes.org/resources/statistics/cost-diabetes>.

² See Tom Dart, *Houston’s Health Crisis: By 2040, One in Five Residents Will Be Diabetic*, The Guardian, Feb. 11, 2016, available at <https://www.theguardian.com/cities/2016/feb/11/houston-health-crisis-diabetes-sugar-cars-diabetic>.

³ *Supra* note 1.

⁴ *Supra* note 1.

⁵ Carolyn Y. Johnson, *Why treating diabetes keeps getting more expensive*, WASH. POST (Oct. 31, 2016), <https://www.washingtonpost.com/news/wonk/wp/2016/10/31/why-insulin-prices-have-kept-rising-for-95-years/>.

2. Defendants Eli Lilly, Novo Nordisk and Sanofi (collectively, “Manufacturer Defendants”) manufacture the vast majority of insulins and other diabetes medications currently on the market in the United States.

3. Defendants CVS Caremark, Express Scripts, OptumRx and Aetna Rx (collectively “PBM Defendants”) manage the pharmacy benefits for the vast majority of individuals in the United States. As part of this work, PBM Defendants establish national formularies that, among other things, set the baseline for which diabetes medications are covered by insurance and which are not.

4. Over the course of the last fifteen years, Manufacturer Defendants have in lockstep raised the reported prices of their respective diabetes drugs in an astounding manner.

5. Insulins that today cost Manufacturer Defendants just \$5 to produce and that were originally priced at \$20 when released in the late 1990s, now range between \$300 and \$700.⁶

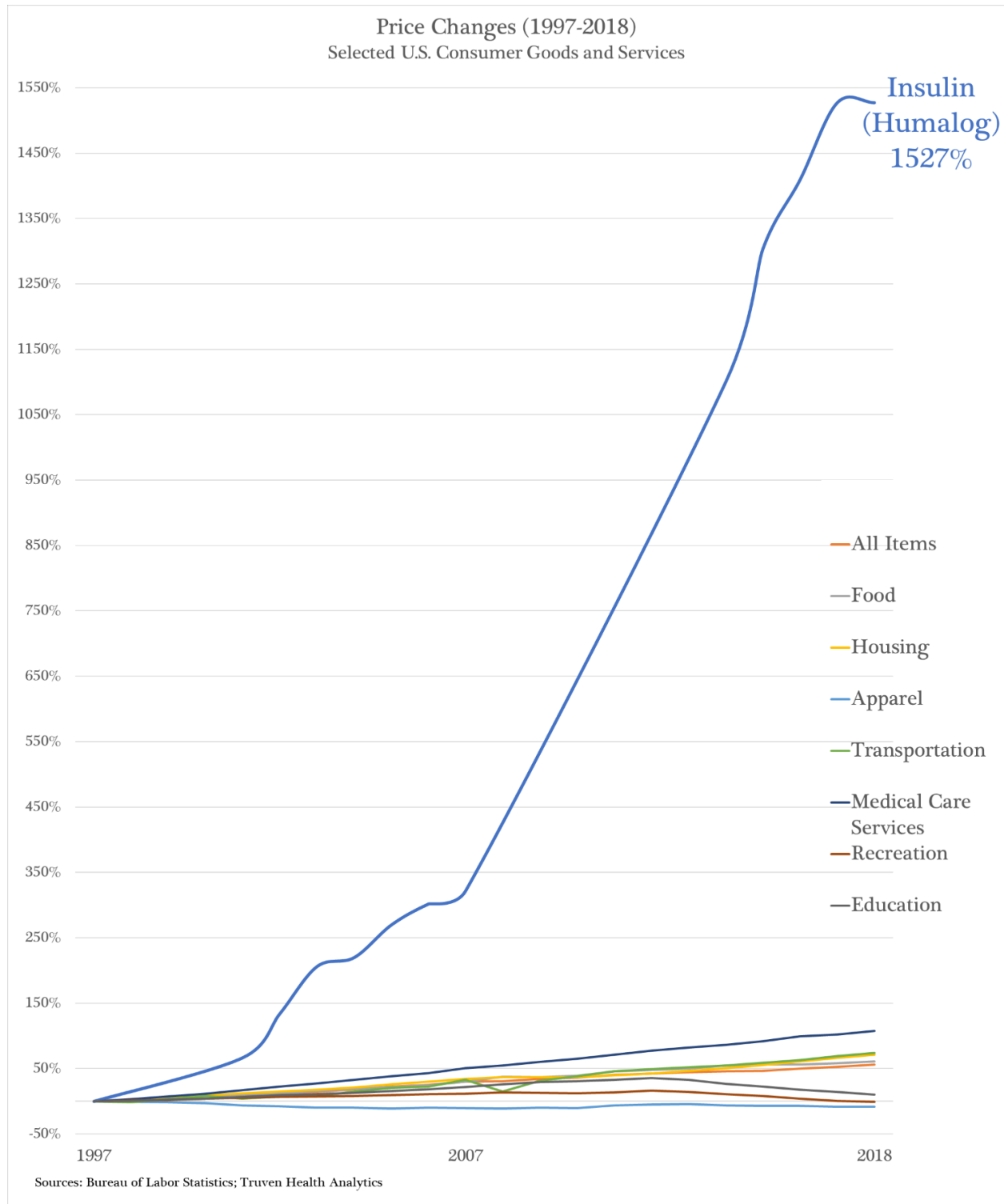
6. In the last decade alone, Manufacturer Defendants have in tandem increased the prices of their insulins up to 1000%, taking the same price increase down to the decimal point within a few days of each other.⁷

7. Figure 1 illustrates the rate in which Defendant Eli Lilly raised the price of its analog insulin, Humalog, compared to the rate of inflation for select consumer goods from 1997-2018.

⁶ See Dzintars Gotham, Melissa J. Barber, Andrew Hill, *Production Costs And Potential Prices For Biosimilars Of Human Insulin And Insulin Analogues*, BMJ Global Health, Vol. 3, Issue 5, available at <https://gh.bmj.com/content/3/5/e000850>; Table 1 of this Complaint.

⁷ See Irl B. Hirsch, MD, *Changing Cost of Insulin Therapy in the U.S.* (Mar. 6, 2016), http://professional.diabetes.org/files/media/Changing_Cost_Insulin.pdf; Figure 1 of this Complaint.

Figure 1: Price Increase of Insulin vs. Selected Consumer Goods from 1997-2018



8. Remarkably, nothing about these medications has *changed* during that time period; today's \$350 drug is the exact same one Defendants sold decades ago for \$20.⁸

9. The current exorbitant price stands in stark contrast to insulin's origins: the discoverers sold the original patent for \$1 to ensure that the medication would remain affordable. Today, insulin has become the poster child for pharmaceutical price gouging.

10. It has now become apparent that the reason behind the lockstep price increases is a conspiracy between PBM and Manufacturer Defendants to create a secret spread between the reported price for diabetic treatments (on which Harris County's payments are based) and the true net price of those same drugs.⁹

11. This conspiracy between Manufacturer and PBM Defendants is at the root of the instant complaint and referred to herein as the "Insulin Pricing Scheme."¹⁰

12. Both Manufacturer and PBM Defendants play vital roles and profit immensely from the Insulin Pricing Scheme.

13. Given their market power and role in formulary and plan design, PBM Defendants wield enormous control over drug purchasing behavior.

⁸ Indianapolis Business Journal, *Lilly Insulin Prices Under Microscope*, The Republic, Sept. 2, 2017, available at http://www.therepublic.com/2017/09/03/lilly_insulin_prices_under_microscope/#:~:targetText=Lilly%20launched%20Humalog%20in%201996,month's%20supply%20for%20many%20patients.&targetText=Instead%2C%20the%20company%20said%2C%20they,negotiate%20drug%20prices%20for%20insurers; see also Table 1 of this Complaint.

⁹ For the purposes of this Complaint, "net price" refers to Manufacturer Defendants' reported price minus all payments made by Manufacturer Defendants to PBM Defendants.

¹⁰ The diabetes medications at issue in this case are Eli Lilly's Humulin N, Humulin R, Humalog, Trulicity and Basaglar; Sanofi's Lantus, Toujeo, Soliqua and Apidra; and Novo Nordisk's Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza and Ozempic. All of these drugs are insulins, except Trulicity, Victoza and Ozempic, which are non-insulin medications used in conjunction with insulins to treat Type 2 diabetes. While these drugs are clinically different than insulins, the relevant facts in this Complaint regarding Defendants' fraudulent pricing scheme apply equally to Trulicity, Victoza and Ozempic. For the purposes of this Complaint, the Insulin Pricing Scheme includes the non-insulin drugs Trulicity, Victoza and Ozempic.

14. PBM Defendants represent both publicly and to their clients that they use their market power to drive down prices for diabetes medications by forcing manufacturers to compete on price for formulary placement.

15. This representation is patently false. Instead, PBM Defendants exploit their market power to cause substantial increases in the price of diabetes medications in order to create massive profits for themselves and Manufacturer Defendants—entirely at the cost of consumers and employers, such as Harris County, who provide employee health benefits.

16. To gain formulary access, Manufacturer Defendants artificially and willingly raise their reported prices, and then secretly refund a significant portion of that price back to PBM Defendants. These refunds are provided under a variety of labels—rebates, discounts, credits, concession fees, etc.¹¹ But, however they are described, they are a *quid pro quo* for formulary inclusion.

17. PBMs then grant formulary status based upon the highest inflated price and the largest refund amount.

18. This Insulin Pricing Scheme creates a “best of both worlds” scenario for Defendants. Manufacturer Defendants are able to make these secret payments to buy preferred formulary position—which significantly increases their revenue—without sacrificing their profit margins. PBM Defendants profit from the inflated reported price by: (1) retaining a significant percentage of Manufacturer Defendants’ payments; (2)

¹¹ In the context of this Complaint, the terms “refunds” and “rebates” are defined as all payments or financial benefits of any kind conferred by the Manufacturer Defendants to PBM Defendants, either directly via contract or indirectly via Manufacturer-controlled intermediaries. By way of example, “refunds” and “rebates” includes rebates, administrative fees, volume discounts, price or margin guarantees and any other form of consideration exchanged.

pocketing an additional pricing spread between what a payor pays the PBM for an insulin script based on this inflated price and a lower price that the PBM reimburses the pharmacy for the same drug (“Pharmacy Spread”); and (3) diverting sales to their profitable mail order pharmacies.

19. The Insulin Pricing Scheme has resulted in record profits for Defendants at the expense of Plaintiff Harris County.

20. Harris County now spends more money on diabetes medications than for medications related to any other disease.

21. In 2015 alone, the amount that Harris County spent on diabetes medications increased over 60% from the previous year.

22. Since 2013, Harris County has spent more than \$27 million on the at issue diabetes medications.¹²

23. A substantial portion of this \$27 million is attributable to Defendants’ inflated prices that did not arise from transparent market forces, but rather from the secret dealings between Manufacturer and PBM Defendants—the Insulin Pricing Scheme described herein.

24. This action alleges that Defendants violated the Racketeer Influenced And Corrupt Organizations Act, the Texas Deceptive Trade Practices Act and various Texas common laws by engaging in the Insulin Pricing Scheme. This scheme directly and foreseeably caused and continues to cause harm to Harris County.

¹² See **Appendix A** attached hereto for a chart detailing Harris County’s spends on the at issue drugs from 2013-2018. To note, 2013-2018 is only a subset of the damages period alleged in this Complaint.

25. This action seeks damages, damage multipliers, attorneys' fees, costs and injunctive relief to address and abate the harm caused by the Insulin Pricing Scheme.

26. The relevant period for damages alleged in this Complaint is from 2003 continuing through the present.

II. PARTIES

A. Plaintiff

27. **Plaintiff, Harris County**, is a body corporate and politic under the laws of the State of Texas.

28. The Harris County government serves its almost five (5) million residents by providing vital services throughout the County. As a large government employer, Harris County provides health benefits to approximately 38,000 employees, retirees and their dependents ("Beneficiaries"). One of the benefits that Harris County offers its Beneficiaries is subsidizing their purchases of the pharmaceutical drugs, including diabetes medications, they need to survive. Harris County also purchases diabetes medications to administer directly to inmates in Harris County jails.

29. As detailed in Appendix A, Harris County spends millions of dollars every year on the at issue drugs.

30. Any increase in spending can have a detrimental effect on Harris County's overall budget and, in turn, negatively impact its ability to provide necessary services to the community.

31. The Insulin Pricing Scheme has had such an effect.

B. Manufacturer Defendants

32. **Defendant Eli Lilly and Company (“Eli Lilly)** is a corporation organized and existing under the laws of the State of Indiana and has a principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

33. Eli Lilly may be served through its registered agent: National Registered Agents, Inc., 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

34. In Texas and nationally, Eli Lilly manufactures, promotes and distributes several diabetes medications paid for by Plaintiff and at issue in this case: Humulin N, Humulin R, Humalog, Trulicity and Basaglar.

35. Eli Lilly’s global revenues in 2018 were \$3.2 billion from Trulicity, \$2.99 billion from Humalog, \$1.33 billion from Humulin and \$801 million from Basaglar.¹³

36. Eli Lilly’s global revenues in 2017 were \$2.03 billion from Trulicity, \$2.85 billion from Humalog, \$1.33 billion from Humulin and \$432 million from Basaglar.¹⁴

37. Eli Lilly transacts business in Texas, targeting the Harris County market for its products, including the diabetes medications at issue in this lawsuit.

38. Eli Lilly employs sales representatives throughout Texas, including in Harris County, to promote and sell Humulin N, Humulin R, Humalog, Trulicity and Basaglar. For example, Eli Lilly recently advertised online that it was seeking sales representatives in its diabetes primary care division to service Houston, Texas and the surrounding communities.¹⁵

¹³ Eli Lilly, Annual Report (Form 10-K) (Dec. 31, 2018).

¹⁴ *Id.*

¹⁵ *See* https://careers.lilly.com/business/custom_fields.multipleregion/north%20america/410/5.

39. Eli Lilly also directs advertising and informational materials to Harris County physicians and potential users of Eli Lilly's products.

40. At all times relevant hereto, Eli Lilly published its reported prices of its diabetes medications at issue in this lawsuit throughout the United States and Texas, including in Harris County.

41. Between 2013-2018 alone (a subset of the total damages period at issue), Harris County spent over \$11.9 million on Eli Lilly's at issue drugs.

42. **Defendant Sanofi-Aventis U.S. LLC ("Sanofi")** is a Delaware limited liability company with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

43. Sanofi may be served through its registered agent: Corporation Service Company DBS CSC – Lawyers Incorporating Service Company, 211 East 7th Street, Suite 620, Austin, Texas 78701.

44. Sanofi manufactures, promotes and distributes pharmaceutical drugs both in Texas and nationally, including insulins and diabetes medications paid for by Plaintiff and at issue in this case: Lantus, Toujeo, Soliqua and Apidra.

45. Sanofi's global revenues in 2018 were \$3.9 billion from Lantus, \$923 million from Toujeo, \$389 million from Apidra and \$79 million for Soliqua.¹⁶

46. Sanofi's global revenues in 2018 were \$5.08 billion from Lantus and \$896 million from Toujeo, \$414 million from Apidra and \$28.5 million from Soliqua.¹⁷

47. Sanofi transacts business in Texas, targeting the Harris County market for its products, including the diabetes medications at issue in this lawsuit.

¹⁶ Sanofi, Annual Report (Form 20-F) (Dec. 31, 2018).

¹⁷ *Id.*

48. Sanofi employs sales representatives throughout Texas, including in Harris County, to promote and sell Lantus, Toujeo, Soliqua and Apidra. For example, Sanofi recently advertised online that it was seeking Diabetes Specialty Sales Representatives in Texas.¹⁸

49. Sanofi also directs advertising and informational materials to Texas physicians and potential users of Sanofi's products.

50. At all times relevant hereto, Sanofi published its reported prices of its diabetes medications at issue in this lawsuit throughout the United States and Texas, including in Harris County.

51. Between 2013-2018 alone (a subset of the total damages period at issue), Harris County spent over \$6.6 million on Sanofi's at issue drugs.

52. **Defendant Novo Nordisk Inc. ("Novo Nordisk")** is a Delaware corporation. Its headquarters are at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

53. Novo Nordisk may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

54. Novo Nordisk manufactures, promotes and distributes pharmaceutical drugs both in Texas and nationally, including insulins and diabetic medications paid for by Plaintiff and at issue in this case: Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza and Ozempic.

¹⁸ See <https://jobs.sanofi.us/search-jobs/texas/Texas%2C%20US/507-18104/1/3/6252001-4736286/31x25044/-99x25061/50/2>.

55. Novo Nordisk's global revenues in 2018 were \$4.19 billion from Novolog, \$1.66 billion from Levemir, \$1.19 billion from Tresiba and \$3.61 billion from Victoza.¹⁹

56. Nordisk's global revenues in 2017 were \$1.65 billion from Novolog, \$1.05 billion from Levemir, \$781.4 million from Tresiba and \$2.68 billion from Victoza.²⁰

57. Novo Nordisk transacts business in Texas, targeting the Harris County market for its products, including the diabetes medications at issue in this lawsuit.

58. Novo Nordisk employs sales representatives throughout Texas, including in Harris County, to promote and sell Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza and Ozempic. For example, Novo Nordisk recently advertised online that it was seeking Pharma Field Sales—Diabetes Care Specialists in Texas.²¹

59. Novo Nordisk also directs advertising and informational materials to Texas physicians and potential users of Novo Nordisk's products.

60. At all times relevant hereto, Novo Nordisk published its reported prices of its diabetes medications at issue in this lawsuit throughout the United States and Texas, including in Harris County.

61. Between 2013-2018 alone (a subset of the total damages period at issue), Harris County spent over \$8.9 million on Novo Nordisk's at issue drugs.

62. Collectively, Defendants Eli Lilly, Novo Nordisk and Sanofi are referred to as "Manufacturer Defendants."

¹⁹ Novo Nordisk, Annual Report (Form 20-F) (Dec. 31, 2018).

²⁰ Novo Nordisk, Annual Report (Form 20-F) (Dec. 31, 2017).

²¹ See <https://www.novonordisk-jobs.com/search/?createNewAlert=false&q=&locationsearch=texas>.

C. PBM Defendants

63. **Defendant CVS Health Corporation** (“CVS Health”) is a corporation organized under the laws of Delaware and headquartered at One CVS Drive, Woonsocket, Rhode Island 02895. CVS Health transacts business and has locations throughout the United States and Texas.

64. CVS Health may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

65. **Defendant Caremark Rx, L.L.C.** is a Delaware limited liability company and an immediate or indirect parent of many subsidiaries, including pharmacy benefit management and mail order subsidiaries. Caremark Rx, L.L.C. is a subsidiary of Defendant CVS Health and its principal place of business is at the same location as CVS Health.

66. Caremark Rx, L.L.C. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

67. **Defendant Caremark L.L.C.** is a California limited liability company whose principal place of business is at the same location as CVS Health. Caremark, L.L.C. is a subsidiary of CVS Health. Caremark, L.L.C. is also the direct or indirect parent of dozens of limited liability companies all over the U.S. that provide mail-order pharmacy services in the U.S. and in Texas.

68. Caremark L.L.C. may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

69. **Defendant CaremarkPCS Health, L.L.C.** is a Delaware limited liability company whose principal place of business is at the same location as CVS Health. CVS Health is the direct or indirect parent company of CaremarkPCS Health LLC.

70. CaremarkPCS Health LLC, doing business as CVS Caremark, provides pharmacy benefit management services and has been registered to do business in Texas since at least 2009.

71. CaremarkPCS Health, L.L.C. may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

72. **Defendant Caremark Texas Mail Pharmacy, LLC**, doing business as CVS Caremark, is a Texas limited liability company whose principal place of business is at the same location as CVS Health.

73. Caremark Texas Mail Pharmacy, LLC may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

74. Caremark Texas Mail Pharmacy, LLC is licensed with the Texas Board of Pharmacy and is registered with the Drug Enforcement Administration (“DEA”) to dispense controlled substances, including diabetes medications.

75. Collectively, Defendants CVS Health Corporation, Caremark Rx, L.L.C., Caremark, L.L.C., CaremarkPCS Health, L.L.C and Caremark Texas Mail Pharmacy, LLC are referred to as “CVS Caremark.”

76. CVS Caremark is named as a defendant in its capacities as a PBM and mail order pharmacy.

77. In its capacity as a PBM, CVS Caremark negotiates on behalf of payors and insurers with Novo Nordisk, Eli Lilly and Sanofi regarding the price of diabetes

medications, as well as for the placement of these firms' diabetes medications on CVS Caremark's drug formularies.

78. CVS Caremark filled or managed approximately 1.9 billion prescriptions during the year ending December 31, 2018.²²

79. CVS Caremark has the largest PBM market share based on total prescription claims managed, representing 36% of the market.²³ CVS Caremark's pharmacy services segment, which includes PBM activities, but not its retail/long-term care segment, generated \$120 billion in total revenues last year.²⁴

80. CVS Caremark describes its PBM business as follows:

[CVS Caremark's] formularies provide recommended products in numerous drug classes to help ensure member access to clinically appropriate drugs with alternatives within a class under the client's pharmacy benefit plan, **while helping to drive the lowest net cost for clients** that select one of [CVS Caremark's] formularies.²⁵

81. At all times relevant hereto, CVS Caremark derived substantial revenue providing pharmacy benefits in Texas, including in Harris County.

82. At all times relevant hereto, CVS Caremark derived substantial revenue providing mail order pharmacy services in Texas, including in Harris County.

83. At all times relevant hereto, CVS Caremark offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that are used nationwide, including in Texas and Harris County. At all times relevant hereto,

²² CVS Caremark Annual Report (Form 10-K) (Dec. 31, 2018).

²³ National Community Pharmacists Association, PBM Resources, <http://www.ncpanet.org/advocacy/thetools/pbm-resources>.

²⁴ Ed Kaplan & Wendy Pongracz, *Negotiating and Drafting Pharmacy Benefit Manager Contracts for Self-Insured Plans*, Strafford (June 21, 2016), <http://media.straffordpub.com/products/negotiating-and-drafting-pharmacy-benefit-manager-contracts-for-self-funded-plans-2016-06-21/presentation.pdf>.

²⁵ CVS Caremark, Annual Report (Form 10-K) (Dec. 31, 2018).

those formularies included diabetes medications, including those at issue in this Complaint.

84. At all times relevant hereto, CVS Caremark dispensed diabetes medications, including diabetes medications at issue in this Complaint, nationwide and in Texas, including in Harris County, through its mail order pharmacies.

85. **Defendant Express Scripts Holding Company** is a Delaware corporation. Its principal place of business is at 1 Express Way, St. Louis, Missouri 63121.

86. Express Scripts Holding Company may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

87. **Defendant Express Scripts, Inc.** is a corporation organized under the laws of Delaware and headquartered at 1 Express Way, St. Louis, Missouri 63121.

88. **Express Scripts, Inc.** may be served through its registered agent: Corporation Service Company DBS CSC – Lawyers Incorporating Service Company, 211 East 7th Street, Suite 620, Austin, Texas 78701.

89. **Defendant ESI Mail Pharmacy Service, Inc.** is a Delaware corporation with its principal place of business in St. Louis, Missouri.

90. Defendant ESI Mail Pharmacy Service, Inc. may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

91. ESI Mail Pharmacy Services, Inc. is licensed as an out-of-state prescription drug distributor with the Texas Department of State Health Services.

92. **Defendant Express Scripts Pharmacy, Inc.** is a Delaware corporation with its principal place of business in St. Louis, Missouri.

93. Defendant Express Scripts Pharmacy, Inc. may be served through its registered agent: Corporation Service Company DBS CSC – Lawyers Incorporating Service Company, 211 East 7th Street, Suite 620, Austin, Texas 78701.

94. Defendants Express Scripts, Inc., ESI Mail Pharmacy Service, Inc. and Express Scripts Pharmacy, Inc. are subsidiaries of Defendant Express Scripts Holdings Company.

95. Collectively, Defendant Express Scripts, Inc., Defendant Express Scripts Holding Company, Defendant ESI Mail Pharmacy Service, Inc. and Defendant Express Scripts Pharmacy, Inc. are referred to as “Express Scripts.”

96. Express Scripts is named as a defendant in its capacities as a PBM and mail order pharmacy.

97. In its capacity as a PBM, Express Scripts negotiates on behalf of payors and insurers with Novo Nordisk, Eli Lilly and Sanofi regarding the purchase price of diabetes medications, as well as for the placement of these firms’ diabetes medications on the PBM’s drug formularies.

98. Prior to merging with Cigna in 2019, Express Scripts was the largest independent PBM in the United States.²⁶ During the relevant period of this Complaint, Express Scripts controlled 30% of the PBM market.²⁷

99. In 2017, annual revenue for Express Scripts was over \$100 billion.²⁸

²⁶ Express Scripts, Annual Report (Form 10-K) (Dec. 31, 2017).

²⁷ *See supra* note 23.

²⁸ *See supra* note 26.

100. As of December 31, 2018, more than 68,000 retail pharmacies, representing over 98% of all retail pharmacies in the nation, participated in one or more of Express Scripts' networks.²⁹

101. Express Scripts transacts business throughout the United States and Texas, including in Harris County.

102. Express Scripts describes its PBM business as follows:

Our core PBM services involve management of prescription drug utilization to drive **high quality, cost-effective pharmaceutical care**. We consult with clients to assist in the selection of plan design features that balance clients' requirements for **cost control** with member choice and convenience. We focus our solutions to enable better decisions in four important and interrelated areas: benefit choices, drug choices, pharmacy choices and health choices. As a result, we believe we deliver healthier outcomes, higher member satisfaction and a **more affordable prescription drug benefit**.³⁰

103. At all times relevant hereto, Express Scripts derived substantial revenue providing pharmacy benefits in Texas, including in Harris County.

104. At all times relevant hereto, Express Scripts derived substantial revenue providing mail order pharmacy services in Texas, including in Harris County.

105. At all times relevant hereto, Express Scripts offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that are used nationwide, including in Texas and Harris County. At all times relevant hereto, those formularies included diabetes medications, including those at issue in this Complaint.

²⁹ *Id.*

³⁰ *Id.*

106. At all times relevant hereto, Express Scripts dispensed diabetes medications, including diabetes medications at issue in this Complaint, nationwide and in Texas, including in Harris County, through its mail order pharmacies.

107. **Defendant OptumRx, Inc.** is a corporation organized under the laws of California and headquartered at 2300 Main St., Irvine, California, 92614.

108. OptumRx, Inc. may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

109. OptumRx, Inc. operates as a subsidiary of OptumRx Holdings, LLC, which in turn operates as a subsidiary of Optum, Inc.

110. Optum Rx has been registered to do business in Texas since at least 2010.

111. OptumRx has several mail-order locations licensed with the Texas Board of Pharmacy and registered with the DEA to dispense controlled substances, including diabetes medications.

112. **Defendant Optum, Inc.,** is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing subsidiaries that administer pharmacy benefits, including OptumRx, Inc.

113. Optum, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

114. Collectively, Defendants OptumRx, Inc. and Optum, Inc. are referred to as “OptumRx.”

115. OptumRx is named as a defendant in its capacities as a PBM and mail order pharmacy.

116. OptumRx is a pharmacy benefit manager and, as such, negotiates on behalf of payors with Novo Nordisk, Eli Lilly and Sanofi for the purchase price of the diabetes medications, as well as for the placement of the firms' diabetes medications on the PBM's drug formularies.

117. OptumRx provides pharmacy care services to more than 65 million people in the nation through a network of more than 67,000 retail pharmacies and multiple delivery facilities.³¹

118. In 2018, OptumRx managed more than \$91 billion in pharmaceutical spending, representing 23% of the market.³² OptumRx's 2018 revenue was \$69 billion.³³

119. OptumRx describes its PBM business as follows:

OptumRx is a pharmacy care services company helping clients and more than 66 million members achieve better health outcomes and **lower overall costs through innovative prescription drug benefits management services**, including network claims processing, clinical programs, formulary management and specialty pharmacy care.³⁴

120. At all times relevant hereto, OptumRx derived substantial revenue providing pharmacy benefits in Texas, including in Harris County.

121. At all times relevant hereto, OptumRx derived substantial revenue through its mail order pharmacies in Texas, including in Harris County.

122. At all times relevant hereto, OptumRx offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that

³¹ United Healthcare/OptumRx Annual Report (Form 10-K) (Dec. 31, 2018).

³² See *supra* note 23.

³³ *Id.*

³⁴ UnitedHealth Group, OptumRx Opioid Risk Management Program Leads to Better Outcomes for Patients and Clients (Aug. 22, 2017), <https://www.unitedhealthgroup.com/newsroom/2017/0822opioidriskmanagementprogramhtml>.

are used nationwide, including in Texas and Harris County. At all times relevant hereto, those formularies included diabetes medications, including those at issue in this Complaint.

123. At all times relevant hereto, OptumRx dispensed diabetes medications, including diabetes medications at issue in this Complaint, nationwide and in Texas, including in Harris County, through its mail order pharmacies.

124. **Aetna Rx Home Delivery, LLC** was formed under the laws of Delaware with its principal place of business located in Hartford, CT.

125. Aetna Rx Home Delivery, LLC may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

126. **Aetna Pharmacy Management Services, LLC** was formed under the laws of Delaware, with its principal place of business located in Hartford, CT. Aetna Pharmacy Management Services, LLC is a wholly owned subsidiary of CVS Health.

127. Aetna Pharmacy Management Services, LLC may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

128. Collectively, Aetna Rx Home Delivery, LLC and Aetna Pharmacy Management Services, LLC are referred to as “Aetna Rx.”

129. Aetna Rx is named as a defendant in its capacities as a PBM and mail order pharmacy.

130. In its capacity as a PBM, Aetna Rx negotiates on behalf of payors with Novo Nordisk, Eli Lilly and Sanofi for the purchase price of the diabetes medications, as well as for the placement of the firms’ diabetes medications on Aetna Rx’s drug formularies.

131. At all times relevant hereto, Aetna Rx derived substantial revenue providing pharmacy benefit services in Texas to payors, including in Harris County.

132. At all times relevant hereto, Aetna Rx derived substantial revenue through its mail order pharmacies in Texas, including in Harris County.

133. At all times relevant hereto, Aetna Rx offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that are used nationwide, including in Texas and in Harris County. At all times relevant hereto, those formularies included diabetes medications, including those at issue in this Complaint.

134. At all times relevant hereto, Aetna Rx dispensed diabetes medications, including diabetes medications at issue in this Complaint, nationwide and in Texas, including in Harris County, through its mail order pharmacies.

135. Collectively, CVS Caremark, Optum Rx, Express Scripts and Aetna Rx are referred to as “PBM Defendants.”

III. JURISDICTION AND VENUE

A. Subject Matter Jurisdiction

136. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff’s claims arise under federal law and under 18 U.S.C. § 1964(c) because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962. This Court also has supplemental jurisdiction over the state law claims in this action pursuant to 28 U.S.C. § 1367.

B. Personal Jurisdiction

137. This Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, reported false prices and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the

United States and Texas, including in this District. The scheme and conspiracy has been directed at, and has had the intended effect of, causing injury to persons and local governments residing in, located in, or doing business throughout the United States and Texas, including in this District. This Court also has personal jurisdiction over all Defendants pursuant to Fed. R. Civ. P. 4(k)(1)(A) because they would be subject to the jurisdiction of a court of general jurisdiction in Texas.

138. This Court also has personal jurisdiction over all defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the “ends of justice” require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the Court in a single trial.

C. Venue

139. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), because each Defendant transacts business in, is found in, and/or has agents in this District, and because some of the actions giving rise to the Complaint took place within this District. In particular, at all times during the relevant time period, Defendants provided pharmacy benefit services, provided mail order pharmacy services, employed sales representatives, promoted and sold diabetes medications and published prices of the at issue drugs in this District.

140. Venue is also proper in this District pursuant to 18 U.S.C. § 1965, because all Defendants reside, are found, have an agent or transact their affairs in this District, and the ends of justice require that any Defendant residing elsewhere be brought before this Court.

IV. FACTUAL ALLEGATIONS

A. Diabetes and Insulin Therapy

Diabetes: A Growing Epidemic

141. Diabetes is a disease that occurs when a person's blood glucose, also called blood sugar, is too high. In a non-diabetic person, the pancreas secretes the hormone insulin, which controls the rate at which food is converted to glucose, or sugar, in the blood. When there is not enough insulin or cells stop responding to insulin, too much blood sugar stays in the bloodstream. Over time, that can cause serious health problems, such as heart disease, vision loss and kidney disease.³⁵

142. There are two basic types of diabetes. Roughly 90-95% of diabetics developed the disease because they do not produce enough insulin or have become resistant to the insulin their bodies do produce.³⁶ Known as Type 2, this more common form of diabetes is often developed later in life. While Type 2 patients can initially be treated with tablets, in the long term most patients have to switch to insulin injections.³⁷

143. Type 1 diabetes occurs when a patient completely ceases insulin production.³⁸ In contrast to Type 2 patients, people with Type 1 diabetes do not produce any insulin and, without regular injections of insulin, they will die.

144. Interruptions to a diabetic's insulin regimen can have severe consequences.³⁹ Missed or inadequate insulin therapy can trigger hyperglycemia and then

³⁵ Centers for Disease Control and Prevention, *Diabetes?*, <https://www.cdc.gov/media/presskits/aahd/diabetes.pdf>.

³⁶ *Id.*

³⁷ *Id.*

³⁸ National Institute of Health, *What is Diabetes* (Nov. 2016), <https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes>.

³⁹ Centers for Disease Control and Prevention, *Diabetes?*, <https://www.cdc.gov/media/presskits/aahd/diabetes.pdf>.

diabetic ketoacidosis. Left untreated, diabetic ketoacidosis can lead to loss of consciousness and death within days.

145. Diabetes is the leading cause of blindness, kidney failure and lower limb amputations and is the seventh leading cause of death in the United States despite the availability of effective treatment.⁴⁰

146. The financial burden caused by diabetes is staggering. In 2017, the total direct and indirect cost is estimated to be \$327 billion, of which \$237 billion represents direct costs and \$90 billion results from work-related absenteeism and reduced productivity.⁴¹ Excess costs associated with diabetic medications constitute 43% of the total direct burden, including nearly \$15 billion for insulin.⁴²

147. The number of Americans with diabetes has exploded in the last half century.⁴³ In 1958, only 1.6 million people in the United States had diabetes.⁴⁴ By the turn of the century, that number had grown to over ten (10) million.⁴⁵ Fourteen (14) years later, the count tripled again. Now over thirty (30) million people—9.4% of the country—live with the disease.⁴⁶

⁴⁰ *Id.*

⁴¹ Am. Diabetes Assoc., *Economic Costs of Diabetes in the U.S. in 2017*, March 22, 2018, available at <https://care.diabetesjournals.org/content/diacare/early/2018/03/20/dci18-0007.full.pdf>.

⁴² *Id.*

⁴³ Center for Disease Control and Prevention, National Diabetes Statistics Report, 2017, available at <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.*

Insulin: A Century Old Drug

148. Despite its potentially deadly impact, diabetes is a highly treatable illness. For patients who are able to follow a prescribed treatment plan consistently, the health complications associated with the disease are avoidable.

149. Unlike many high-burden diseases, treatment for diabetes has been available for almost a century.

150. In 1922, Frederick Banting and Charles Best pioneered a technique for removing insulin from an animal pancreas that could then be used to treat diabetes.⁴⁷ After discovery, Banting and Best obtained a patent and then sold it to the University of Toronto for \$1 each (equivalent of \$14 today), explaining “[w]hen the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly.”⁴⁸

151. After purchasing the patent, the University of Toronto contracted with Defendants Eli Lilly and Novo Nordisk to scale their production. Under this arrangement, Eli Lilly and Novo Nordisk were allowed to apply for patents on variations to the manufacturing process.

152. Although early iterations of insulin were immediately perceived as lifesaving,⁴⁹ there have been numerous incremental improvements since its discovery. The

⁴⁷ Valencia Higuera, *Everything You Need to Know About Insulin*, Healthline (Dec. 7, 2016), <http://www.healthline.com/health/type-2-diabetes/insulin>.

⁴⁸ M. Bliss, *The Discovery of Insulin* (2013).

⁴⁹ Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. Eng. J. Med. 1171, 1172 (2015).

earliest insulin was derived from animals and, until the 1980s, was the only treatment for diabetes.⁵⁰

153. While effective, animal-derived insulin created the risk of allergic reaction. This risk was lessened in 1982 when synthetic insulin, known as human insulin, was developed by Defendant Eli Lilly.⁵¹ Eli Lilly marketed this insulin as Humulin.

154. Over a decade later, Eli Lilly released the first analog insulin.

155. Analog insulin refers to laboratory grown and genetically altered insulin. Analogs are slight variations on human insulin to make the injected treatment act more like the insulin naturally produced and regulated by the body.

156. Defendant Eli Lilly developed the first analog insulin, Humalog, in 1996.

157. Other rapid-acting analogs are Defendant Novo Nordisk's Novolog and Defendant Sanofi's Apidra, with similar profiles. Diabetics use these rapid-acting insulins in combination with longer-acting insulins, such as Sanofi's Lantus and Novo Nordisk's Levemir.

158. Manufacturer Defendants introduced these rapid-acting and long-acting analog insulins between 1996 and 2007.

159. In 2015, Sanofi introduced Toujeo, another long-acting insulin also similar to Lantus, however Toujeo is highly concentrated, making injection volume smaller than Lantus.

160. In 2016, Eli Lilly introduced Basaglar, which is a long-acting insulin that is biologically similar to Sanofi's Lantus.

⁵⁰ Irl B. Hirsch, MD, *Changing Cost of Insulin Therapy in the U.S.* (Mar. 6, 2016), http://professional.diabetes.org/files/media/Changing_Cost_Insulin.pdf.

⁵¹ *History of Insulin*, Diabetes.co.uk (2007), <http://www.diabetes.co.uk/insulin/history-of-insulin.html>.

161. Even though insulin was first extracted nearly one-hundred (100) years ago, only Defendants Eli Lilly, Novo Nordisk and Sanofi hold the patents in the United States to manufacture insulin.⁵²

162. Manufacturer Defendants make 99% of the insulins in the market today.⁵³

Current Insulin Landscape

163. While insulin today is generally safer and more convenient to use than when originally developed in 1922, there remain questions whether the overall efficacy of insulin has significantly improved over the last twenty (20) years.

164. For example, while long-acting analogs may have certain advantages over human insulins, such as affording more flexibility around mealtime planning, it has yet to be shown that analogs lead to better long-term outcomes.⁵⁴

165. A recent study published in the Journal of American Medical Association suggests that older human insulins may work just as well as newer analog insulins for patients with Type 2 diabetes.⁵⁵

166. When discussing the latest iterations of insulins, Harvard Medical School professor David Nathan recently stated:

I don't think it takes a cynic such as myself to see most of these [insulins] are being developed to preserve patent protection. The truth is they are marginally different, and the clinical benefits of them over the older drugs have been zero.⁵⁶

⁵² See Greene, *supra* note 49.

⁵³ D. Beran et al, *A perspective on global access to insulin: a descriptive study of the market, trade flows and prices*, DIABETIC MED. 726, 726 (2019).

⁵⁴ *Id.*; see also Riddle MC, Rosenstock J, Gerich J, Insulin Glargine 4002 Study Investigators. The treat-to-target trial: randomized addition of glargine or human NPH insulin to oral therapy of type 2 diabetic patients. *Diabetes Care* 2003.

⁵⁵ Jing Luo, MD, Nazleen F. Khan, MS, Thomas Manetti, MPH, *Implementation of a Health Plan Program for Switching from Analogue to Human Insulin and Glycemic Control Among Medicare Beneficiaries with Type 2 Diabetes*, AMA. 2019;321(4):374-384, January 29, 2019.

⁵⁶ See Johnson, *supra* note 5.

167. Moreover, all of the insulins at issue in this case have either been available in the same form since the late 1990s/early 2000s or are biologically equivalent to insulins that were available then.

168. In addition, in the last ten (10) years, the production costs of insulin have decreased as manufacturers simplified and optimized processes. A September 2018 study published in *BMJ Global Health* calculated that based on production costs, a reasonable price for a year's supply of human insulin is \$48 to \$71 per person and between \$78 and \$133 for analog insulins—which includes delivering a profit to manufacturers.⁵⁷ These figures stand in stark contrast to the \$5,705 that a diabetic spent, on average, for insulin in 2016.⁵⁸

169. Further, while research and development costs often make up a large percentage of the price of a drug, in the case of insulin the initial basic research—original drug discovery and patient trials—was performed one-hundred (100) years ago.

170. Even the more recent costs, such as developing the recombinant DNA fermentation process and the creation of insulin analogs, were incurred decades ago.⁵⁹

171. Despite this decrease in production costs and no new research and development, the reported price of insulins has risen astronomically over the last fifteen (15) years.

⁵⁷ Dzintars Gotham, Melissa J. Barber, Andrew Hill, *Production Costs And Potential Prices For Biosimilars Of Human Insulin And Insulin Analogues*, *BMJ Global Health*, Vol. 3, Issue 5, available at <https://gh.bmj.com/content/3/5/e000850>.

⁵⁸ See Robin Respaut, *U.S. Insulin Costs Per Patient Nearly Doubled From 2012 to 2016: Study*, *Reuters Health News*, January 22, 2019, available at [https://www.reuters.com/article/us-usa-healthcare-diabetes-cost/u-s-insulin-costs-per-patient-nearly-doubled-from-2012-to-2016-study-idUSKCN1PG136#:~:targetText=A%20person%20with%20type%201,Care%20Cost%20Institute%20\(HCCI\)](https://www.reuters.com/article/us-usa-healthcare-diabetes-cost/u-s-insulin-costs-per-patient-nearly-doubled-from-2012-to-2016-study-idUSKCN1PG136#:~:targetText=A%20person%20with%20type%201,Care%20Cost%20Institute%20(HCCI)).

⁵⁹ See Greene, *supra* note 49.

Insulin Adjuncts: Type 2 Medications

172. Over the past decade, Manufacturer Defendants have also released a number of non-insulin medications that help control the level of insulin in the bloodstream of Type 2 diabetics.

173. In 2010, Novo Nordisk released Victoza as an adjunct to insulin to improve glycemic control. In 2014, Eli Lilly released a similar drug, Trulicity, and in 2017, Novo Nordisk did the same with Ozempic.

174. Victoza, Trulicity and Ozempic are all medications known as glucagon-like peptide-1 receptor agonists (“GLP-1”) and are similar to the GLP-1 hormone that is already produced in the body. Each of these drugs can be used in conjunction with insulins to control diabetes.

175. Today, Manufacturer Defendants have a dominant position in the market for all diabetes medications. The following is a list of diabetes medications at issue in this lawsuit:

Table 1: Diabetes medications at issue in this case					
Insulin Type	Action	Name	Company	FDA Approval	Current Reported Price
Human	Rapid-Acting	Humulin R	Eli Lilly	1982	\$178 (vial)
		Humulin R 500	Eli Lilly	1982	\$1,784 (vial) \$689 (pen)
		Novolin R	Novo Nordisk	1991	\$172 (vial)
	Intermediate	Humulin N	Eli Lilly	1982	\$178 (vial) \$566 (pen)
		Humulin 70/30	Eli Lilly	1989	\$178 (vial) \$566 (pen)
		Novolin N	Novo Nordisk	1991	\$172 (vial)
Analog	Rapid-Acting	Humalog	Eli Lilly	1996	\$350 (vial) \$636 (pen)

		Novolog	Novo Nordisk	2000	\$347 (vial) \$671 (pen)
		Apidra	Sanofi	2004	\$341 (vial) \$658 (pen)
	Long-Acting	Lantus	Sanofi	2000	\$ 340 (vial) \$510 (pen)
		Levemir	Novo Nordisk	2005	\$ 370 (vial) \$ 555 (pen)
		Basaglar (Kwikpen)	Eli Lilly	2016	\$392 (pen)
		Toujeo (Solostar)	Sanofi	2015	\$466 (pen) \$622 (max pen)
		Tresiba (FlexTouch)	Novo Nordisk	2015	\$610 (pen – 100u) \$732 (pen – 200u)
Type 2 Medications		Trulicity	Eli Lilly	2014	\$911.28 (pen)
		Victoza	Novo Nordisk	2010	\$774 (2 pens) \$1,161 (3 pens)
		Ozempic	Novo Nordisk	2017	\$973 (pen)
		Soliqua	Sanofi	2016	\$883 (pen)

B. The Dramatic Rise in the Price of Diabetes Medications

176. The Medicare Modernization Act in 2003 installed PBMs as intermediaries to the newly expanded Medicare drug benefit program and, consequently, helped set off PBM Defendants' rise to power (which will be discussed in greater detail in the next section).

177. That same year, the price of insulin began its dramatic rise to its current exorbitant prices.

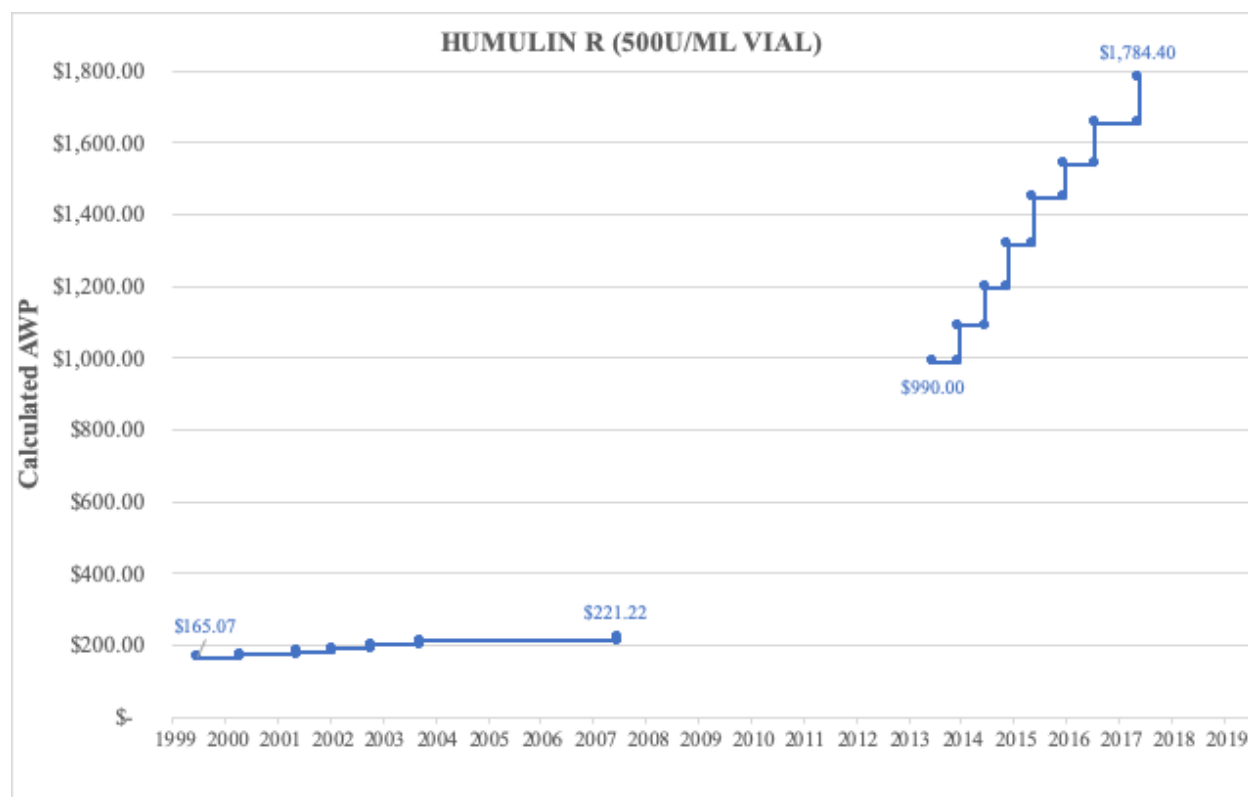
178. Since 2003, the reported price of certain insulins has increased in some cases by more than 1000%; an astounding increase especially when compared to a general inflation rate of 8.3% and a medical inflation rate of 46% in this time period.⁶⁰

⁶⁰ See Hirsch, *supra* note 7.

179. By 2016, the average price per month of the four most popular types of insulin rose to \$450 — and costs continue to rise, so much so that as many as one in four people with diabetes are now skimping on or skipping lifesaving doses.⁶¹

180. Since 1999, Defendant Eli Lilly has raised the price of a vial of Humulin R (500U/ML) from \$165 to \$1784 (See Figure 2).

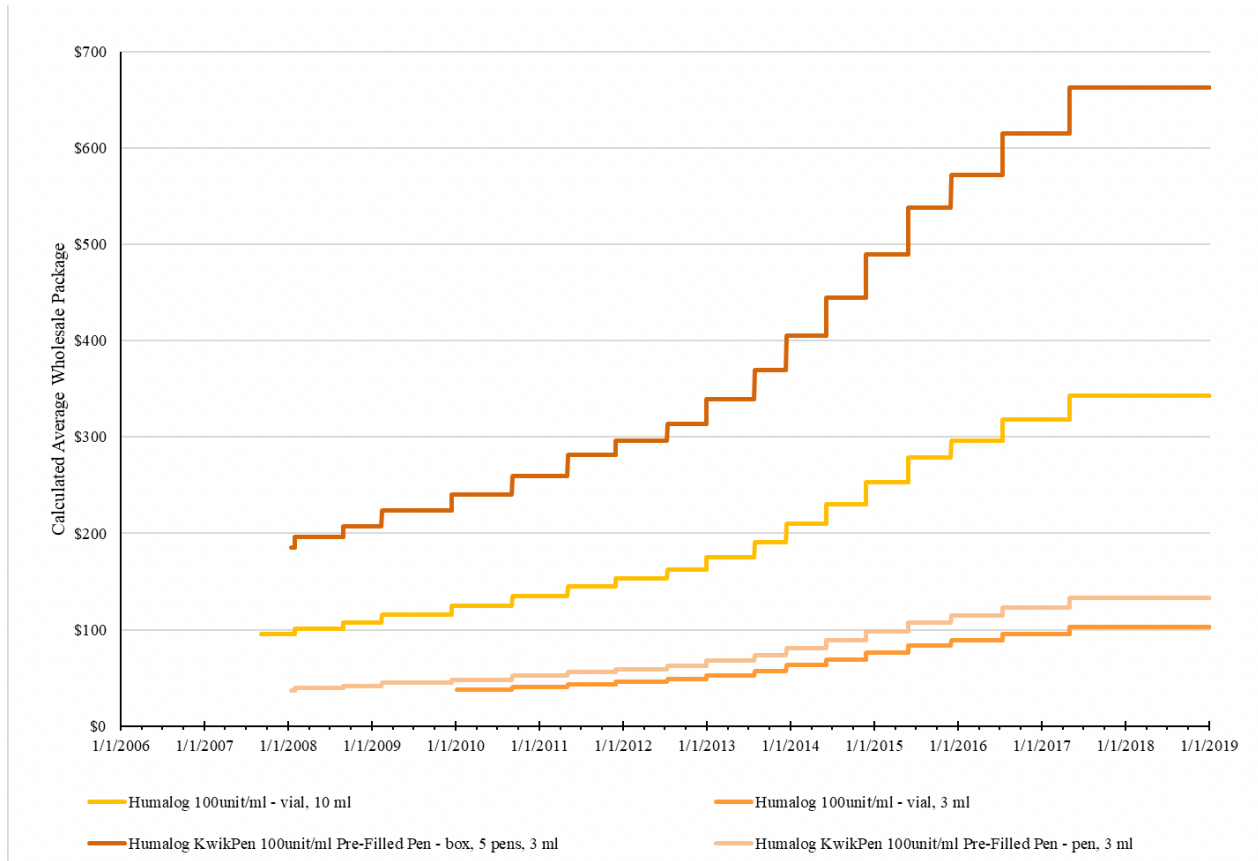
Figure 2: Rising reported prices of Humulin R (500U/ML) from 1999-2019⁶²



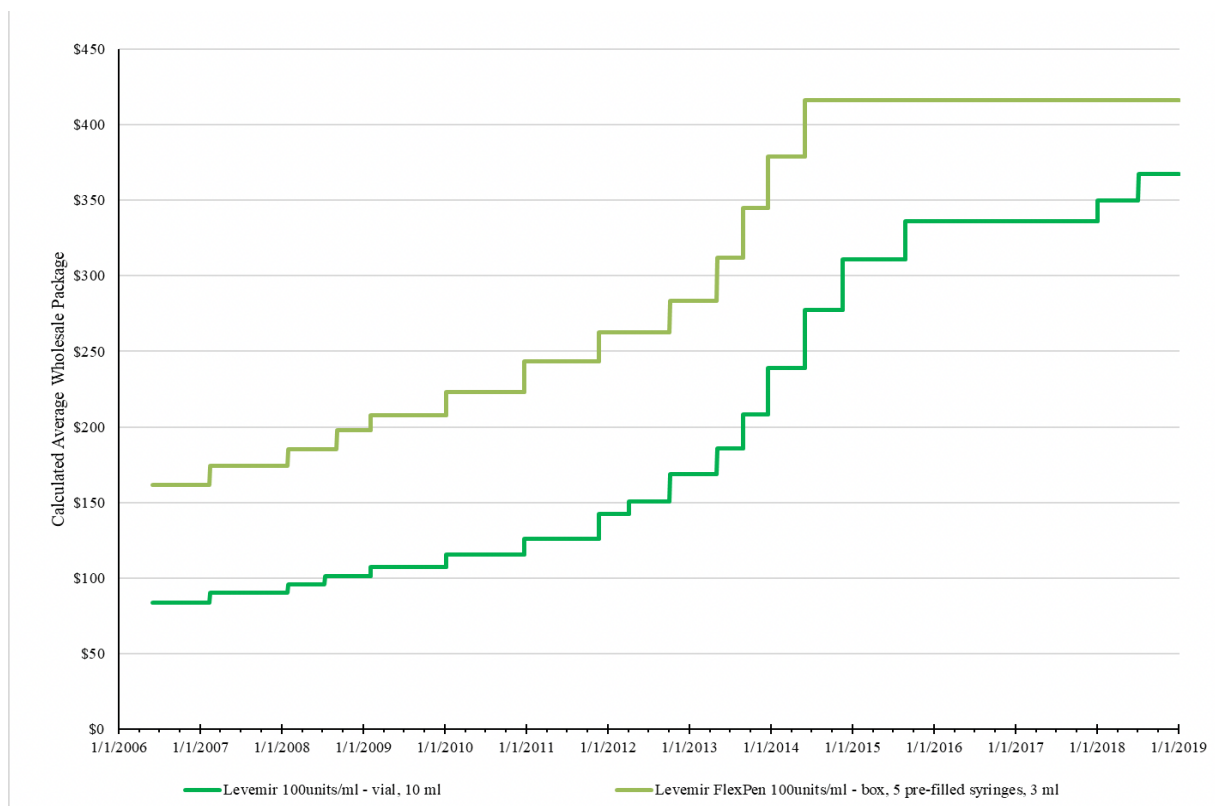
181. Since 2008, Defendant Eli Lilly has raised the reported price for a package of pens of Humalog from less than \$200 to \$663 and from less than \$100 for a box of cartridges to \$343 (See Figure 3).

⁶¹<https://www.nytimes.com/2019/04/03/health/drug-prices-insulin-express-scripts.html>.

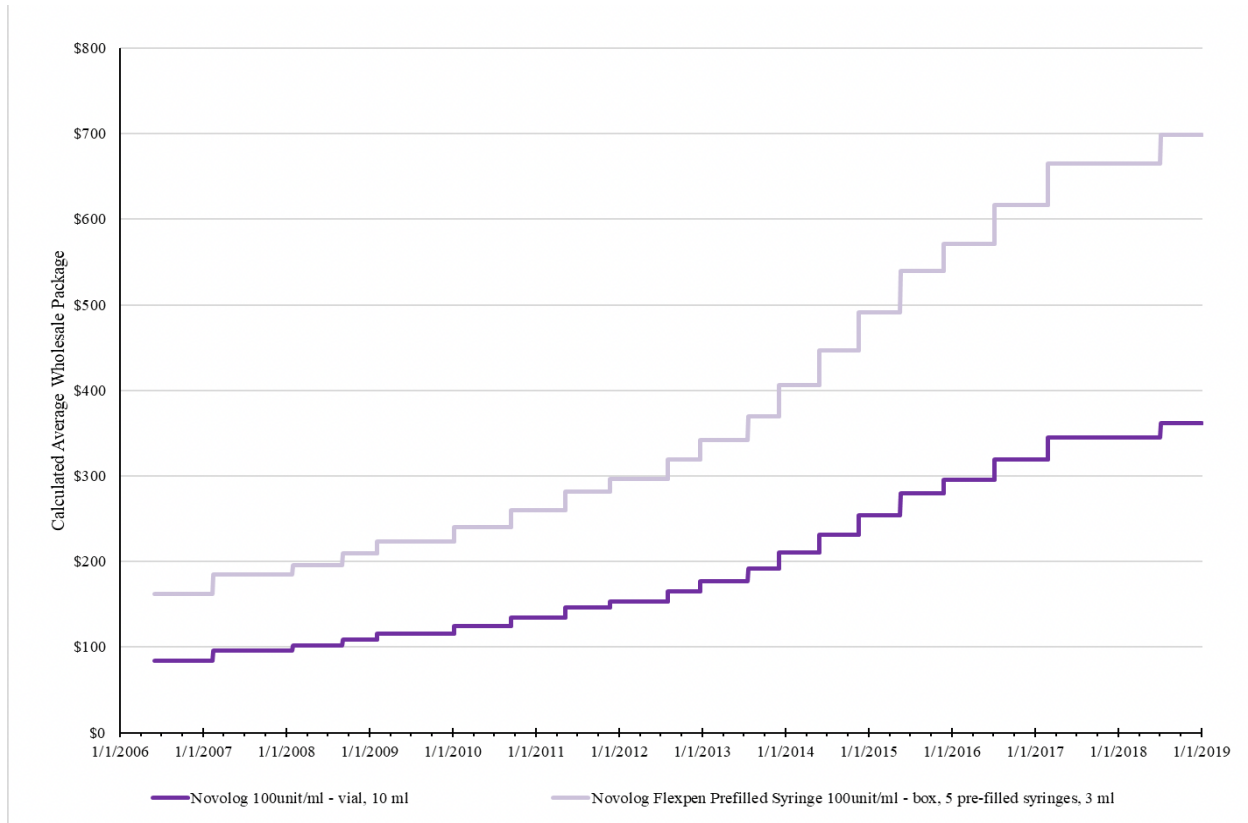
⁶² Eli Lilly did not report the price of Humulin R to all publishing compendiums from 2008-2014.

Figure 3: Rising reported prices of Humalog vials and pens from 2008-2019

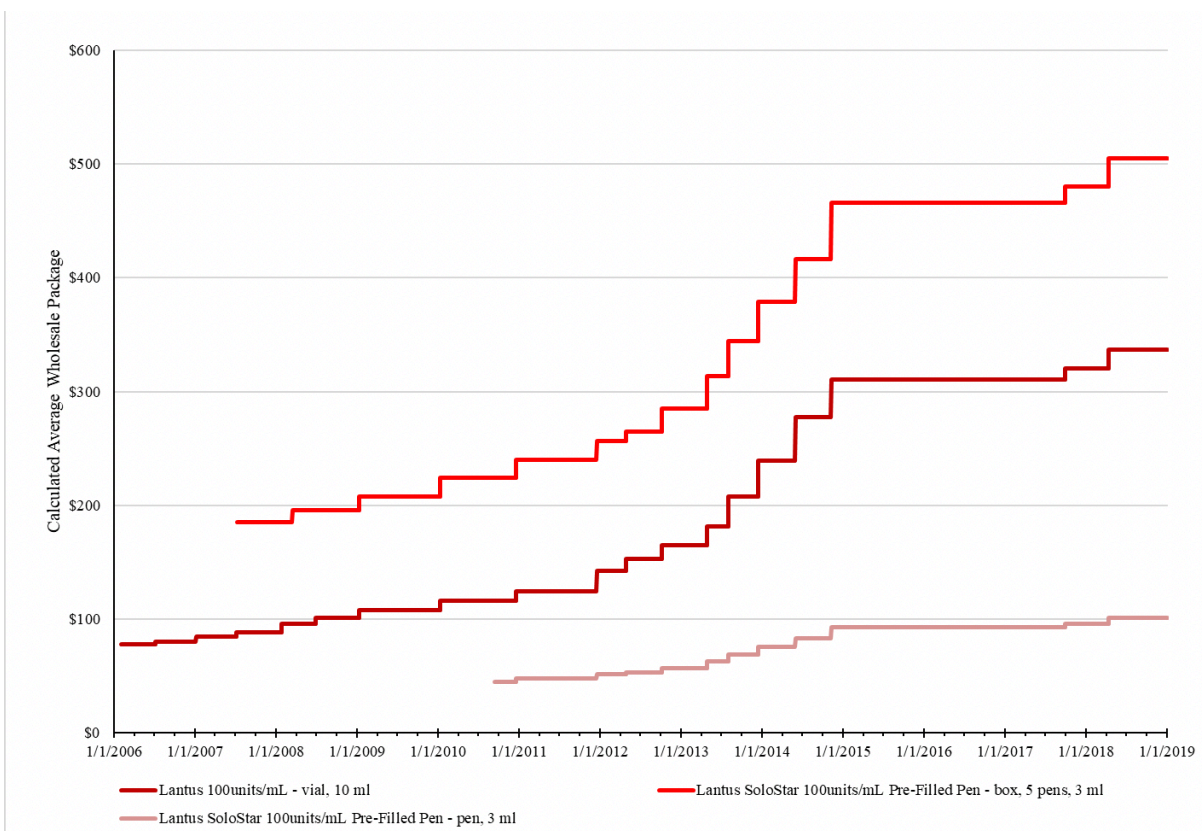
182. Novo Nordisk has also increased its prices—from 2007 to 2018 Levemir rose from \$155 to \$430 for pens and from under \$100 to \$367 per vial (See Figure 4).

Figure 4: Rising reported prices of Levemir 2006-2019

183. From 2007 to 2018, Novo Nordisk raised the price of Novolog from \$160 to \$698 for a package of pens and from less than \$100 to \$362 for a vial (See Figure 5).

Figure 5: Rising reported prices of Novolog vials and pens from 2006-2019

184. Defendant Sanofi has kept pace as well, increasing the reported prices for Lantus, the top-selling analog insulin, from less than \$200 in 2006 to over \$500 in 2019 for a package of pens and from less than \$100 to \$340 for a vial (See Figure 6).

Figure 6: Rising reported prices of Lantus vials and pens from 2006-2019

185. Manufacturer Defendants' non-insulin medications have experienced similar recent price increases. For example, since 2015 Eli Lilly has increased the price of Trulicity almost 50%.

186. Driven by these price hikes, payor spending on diabetes medications, and insulins in particular, has skyrocketed with totals in the tens of billions of dollars. According to the Journal of the American Medical Association, more money is spent per patient on insulin than all other diabetes medications combined.⁶³

⁶³ Johnson, *supra* note 5.

Defendant Manufacturers Have Increased Prices in Lockstep

187. The timing of the price increases reveal that each Manufacturer Defendant has not only dramatically increased reported prices for diabetes treatments, they have acted in collusion by raising prices in perfect lockstep.

188. In thirteen (13) instances since 2009, competitors Sanofi and Novo Nordisk raised the reported prices of their insulins, Lantus and Levemir, in tandem, “taking the same price increase down to the decimal point within a few days of each other.”⁶⁴

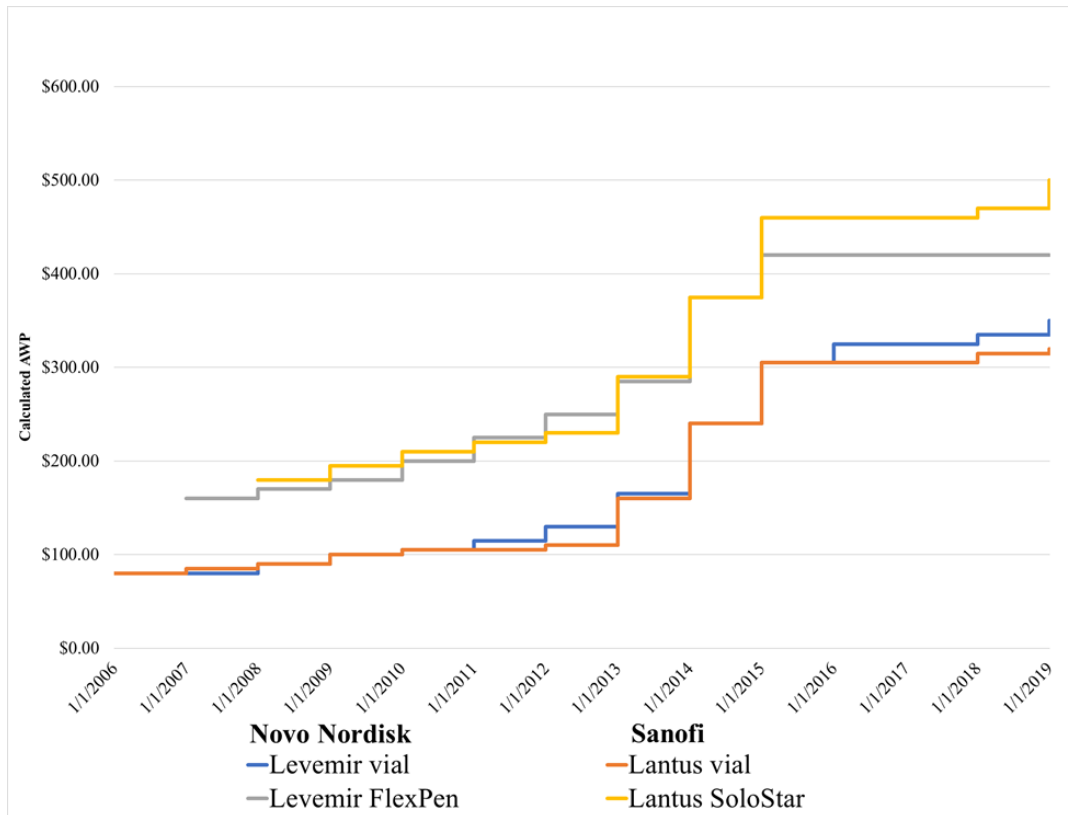
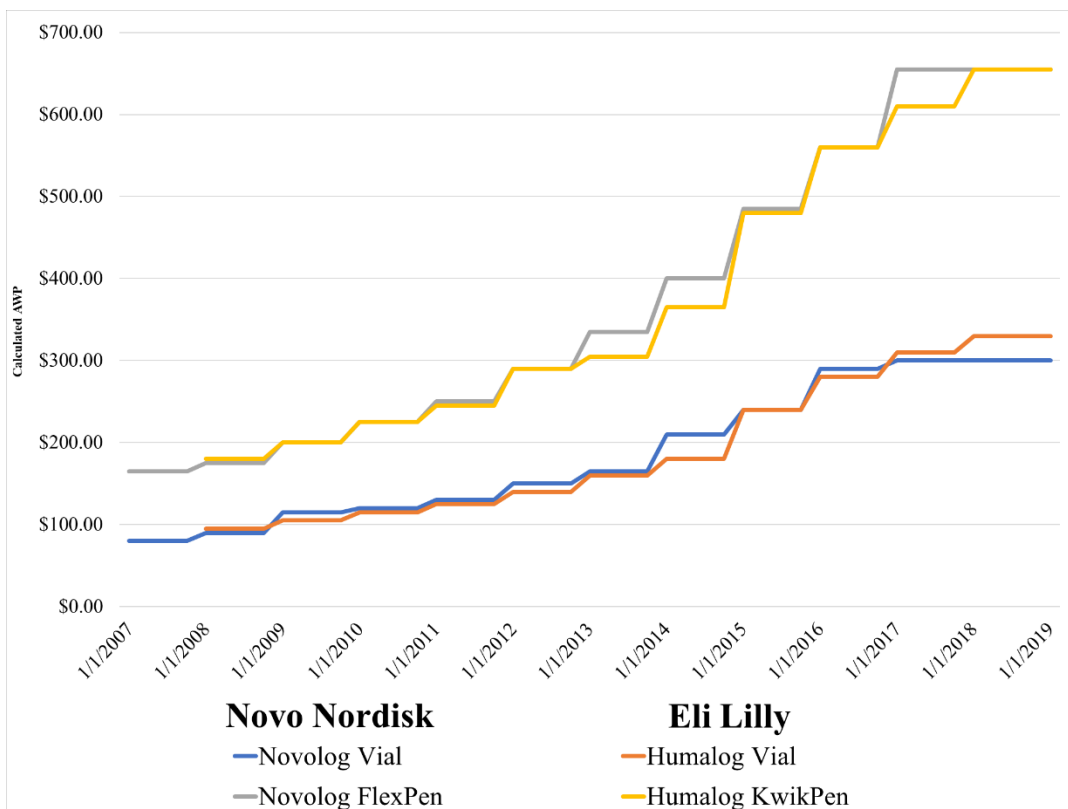
189. This practice of increasing drug prices in lockstep with competitors is known as “shadow pricing” and, as one healthcare analyst put it: “is pretty much a clear signal that your competitor does not intend to price-compete with you.”⁶⁵

190. In 2016, Novo Nordisk and Sanofi’s lockstep increases were responsible for the highest reported drug price increases in the entire pharmaceutical industry.

191. Eli Lilly and Novo Nordisk have engaged in the same lockstep behavior with respect to their rapid-acting analog insulins, Humalog and Novolog. Figure 7 demonstrates this collusive behavior with respect to Lantus and Levemir. Figure 8 demonstrates this behavior with respect to Novolog and Humalog.

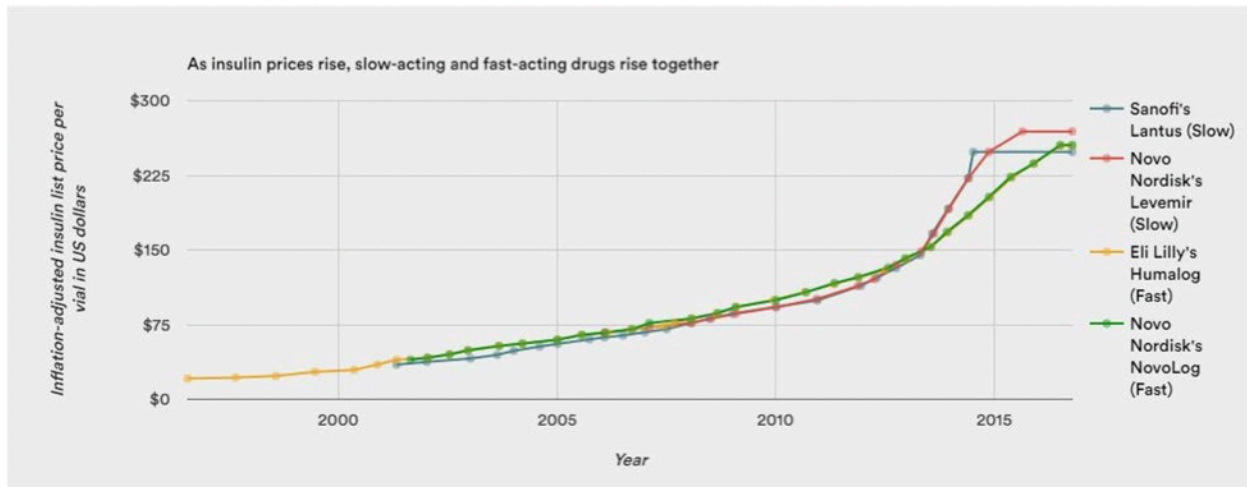
⁶⁴ Robert Langreth, *Hot Drugs Show Sharp Price Hikes in Shadow Market*, Bloomberg (May 6, 2015).

⁶⁵ *Id.*

Figure 7: Rising reported prices of long-acting insulins**Figure 8: Rising reported prices of rapid-acting insulins**

192. Figure 9 shows how, collectively, Manufacturer Defendants have exponentially raised the reported prices of insulin products in near perfect unison.

Figure 9: Rising insulin reported prices from 2000-2015



193. Because of Manufacturer Defendants' collusive price increases, nearly a century after the discovery of insulin the price of diabetes medications has become unaffordable for many diabetics.

194. Governmental entities, like Harris County, who purchase diabetes medications through their health plans and to be administered directly in government-run facilities, have been burdened with paying these skyrocketing prices.

195. In most cases, these payors are paying for nearly identical drugs that were available fifteen to twenty years ago, only now they are paying up to 1000% more.

196. While the reported price for diabetes medications has increased exponentially, the net price tellingly has not.

197. The gap between these two prices—and Defendants' ability to manipulate this pricing disconnect—is a critical element to the Insulin Pricing Scheme and will be discussed in greater detail below. However, to understand the Insulin Pricing Scheme first

requires an understanding of how diabetes medications are distributed and priced in the United States.

C. PBMs and the Pharmaceutical Payment and Supply Chain

Drug Payment and Distribution Chain

198. The prescription drug industry consists of a deliberately opaque network of entities engaged in multiple distribution and payment structures. These entities include drug manufacturers, wholesalers, pharmacies, health plans/third party payors (institutional insurers, self-insured employers), pharmacy benefit managers and patient-consumers.

199. Generally speaking, branded prescription drugs, such as the at issue diabetes medications, are distributed from manufacturer to wholesaler, wholesaler to retail or mail order pharmacy and pharmacy to patient/consumer.

200. The pharmaceutical industry, however, is unique in that the pricing chain is distinct from the distribution chain. The prices for the drugs distributed in the pharmaceutical chain are different for each participating entity: different actors pay different prices set by different entities for the same drugs.

201. There is no transparency in this pricing system; typically, only a brand drug's reported price—also known as its Average Wholesale Price (AWP) or the mathematically-related (for brand drugs) Wholesale Acquisition Cost (WAC)—is available.

202. Drug manufacturers self-report AWP or other prices upon which AWP is based to companies such as First DataBank, Redbook and others who then publish that price.

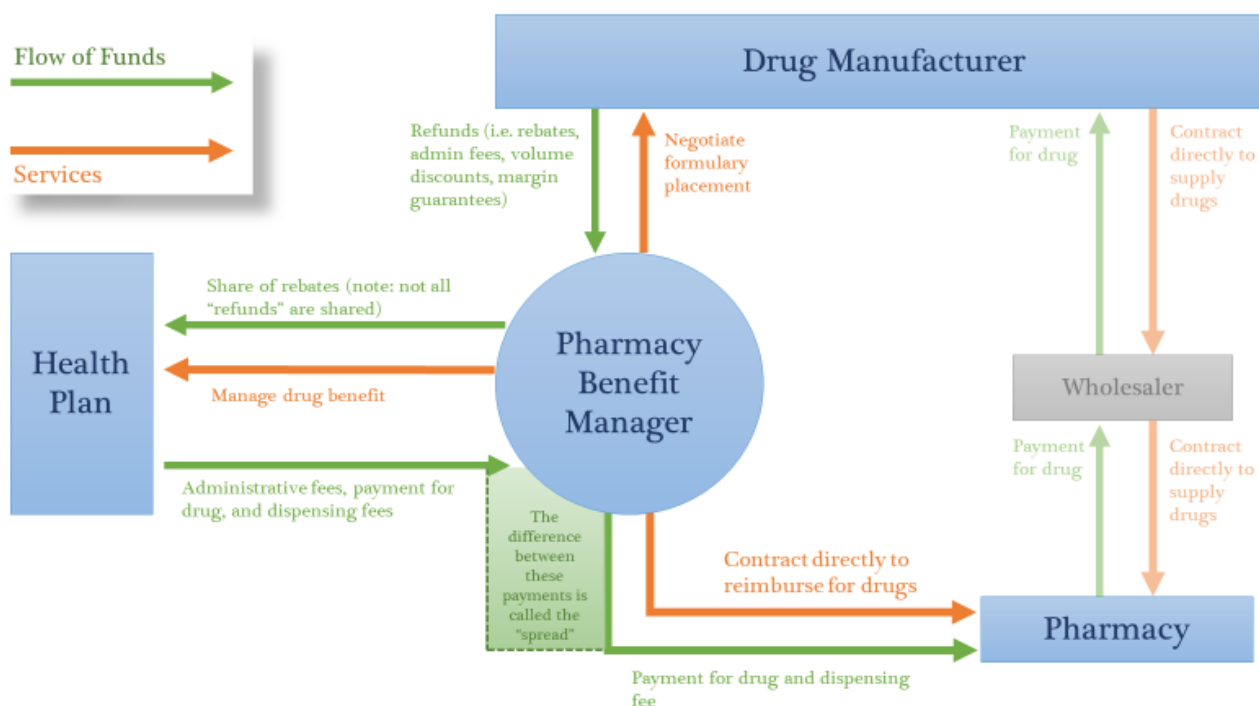
203. AWP persists as the most commonly and continuously used reported price in reimbursement and payment calculations and negotiations.

204. From an administrative perspective, AWP provides a logical starting point for the calculation and communications of how much a payor will pay for a drug.

205. Given the historical use of AWP by all industry participants, one cannot discount the significance of AWP's entrenchment in the complex pharmaceutical payment system.

206. PBMs are at the center of this convoluted payment structure, as illustrated in Figure 10:

Figure 10: Insulin distribution and payment chain



207. PBMs administer payors', such as Harris County's, prescription drug program. A PBM develops the payor's drug formulary, processes claims, creates a network of retail pharmacies, sets the prices that the payor will pay for prescription drugs and is paid by the payor for the drugs utilized by the health plan's beneficiaries.

208. The amount that health plans and payors pay to the PBM for prescription drugs is directly tied to the reported price, often the AWP price less some percentage discount.

209. PBMs also contract with a network of retail pharmacies. Pharmacies agree to dispense drugs to patients and PBMs pay the pharmacies for the drugs dispensed.

210. The amount PBMs pay pharmacies is not the same as the amount paid by the payor. It is instead negotiated between the PBM and the pharmacy and not disclosed.

211. Many PBMs also own mail-order and specialty pharmacies, which purchase and take possession of prescription drugs, including those at issue here, and directly supply those drugs to patients by mail.

212. In addition, and of particular significance here, PBMs contract with pharmaceutical manufacturers, such as Manufacturer Defendants. PBMs negotiate rebates, fees and other concessions with the manufacturers that are paid back to the PBM.

213. These relationships allow PBMs to exert tremendous influence over what drugs are made available to payors, on what terms and at what prices.

214. Thus, PBMs are at the center of the flow of money in the pharmaceutical supply chain—PBMs negotiate the price that payors pay for a prescription drug; they separately negotiate a different price that pharmacies receive for that same drug; and they also negotiate the amount that manufacturers pay back to the PBM for each drug sold.

215. Yet, only the PBMs are privy to the amount that any other entity in this supply chain is paying or receiving for the exact same drugs.

216. This lack of transparency affords Defendants the opportunity to extract billions of dollars from this payment and supply chain without detection.

The Rise of the PBMs in the Pharmaceutical Supply Chain

217. When they first came into existence in the 1960s, PBMs merely provided administrative services to payors by processing claims and maintaining formularies. Over time, however, they have taken on a larger and larger role in the pharmaceutical industry. Today PBMs wield significant control over the drug pricing system.

218. One of the roles PBMs took on was negotiating prices on behalf of payors. In doing so, PBMs affirmatively represented that they were using their leverage to negotiate lower reimbursement rates with pharmacies and discounts from drug manufacturers.⁶⁶

219. In the early 2000s, PBMs started buying pharmacies. When a PBM combines with a pharmacy, they “lose the incentive to police against pharmaceutical company schemes to steer patients to more expensive drugs. Indeed, they may collude in them.”⁶⁷

220. More recently, further consolidation in the industry has afforded PBMs a disproportionate amount of market power.

221. In total, twenty-four (24) different PBM entities have merged or otherwise been absorbed into what are now the PBM Defendants.

222. In addition, each of the most powerful PBM Defendants are now owned by other significant players within the pharmaceutical chain: Express Scripts merged with Cigna in a \$67 billion-dollar deal,⁶⁸ Caremark was bought by the largest pharmacy in the

⁶⁶ Brian Feldman, *Big pharmacies are dismantling the industry that keeps US drug costs even sort-of under control* (Mar. 17, 2016), <https://qz.com/636823/big-pharmacies-are-dismantling-the-industry-that-keeps-us-drug-costs-even-sort-of-under-control/>.

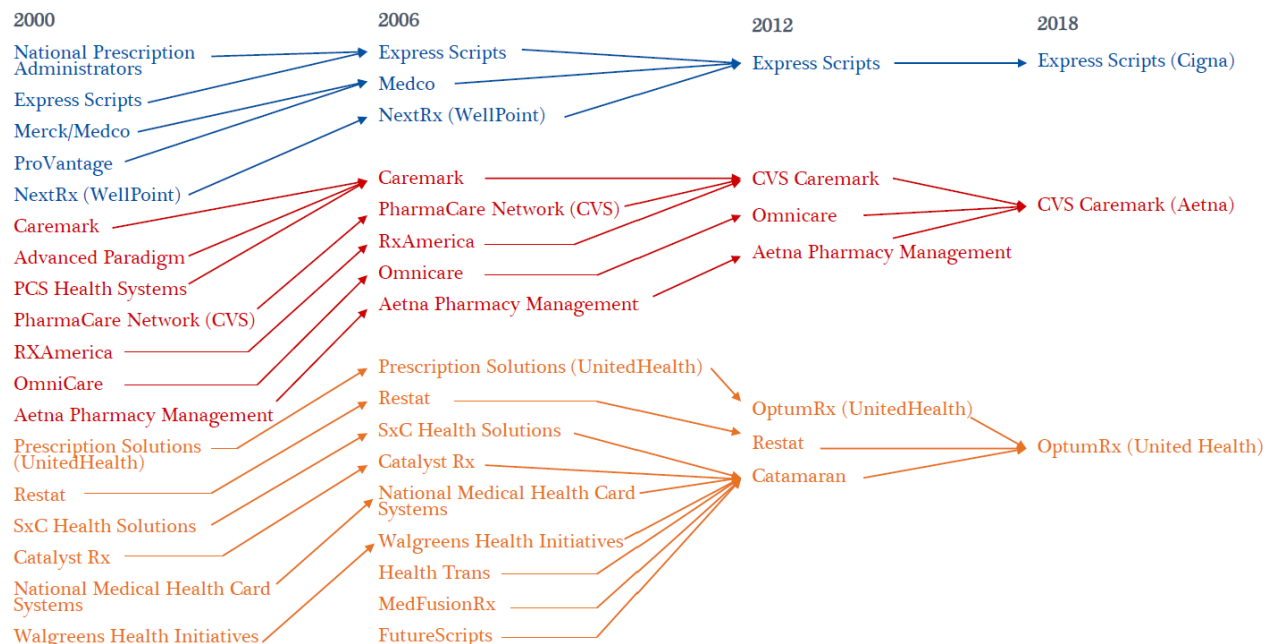
⁶⁷ *Id.*

⁶⁸ See <https://www.cigna.com/about-us/newsroom/innovation/cigna-completes-combination-with-express-scripts>.

United States, CVS for \$21 billion,⁶⁹ CVS also now owns Aetna Rx following a \$69 billion-dollar deal⁷⁰ and OptumRx was acquired by the largest health insurance company in the United States, United Healthcare.⁷¹

223. Figure 11 depicts this consolidation within the PBM market.

Figure 11: PBM consolidation



224. After merging or acquiring all of their competitors and now backed by multi-billion-dollar corporations, PBM Defendants have taken over the market in the past decade—controlling approximately 75% of the private market and managing pharmacy benefits for over 270 million Americans.⁷²

⁶⁹ See https://www.forbes.com/2007/03/16/caremark-approves-update-markets-equity-cx_er_0316markets29.html#77fa558a3380.

⁷⁰ See <https://cvshealth.com/aetna>.

⁷¹ See <https://www.unitedhealthgroup.com/about/history.html>.

⁷² Adam J. Fein, *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute, February 2018.

225. Business is booming for PBM Defendants. Together, they report more than \$300 billion in annual revenue.⁷³

226. PBMs are able to leverage this market power to make outsized profits by exploiting the United States' complex pharmaceutical pricing system. Earlier this year, an industry expert described this imbalance in power, "it's really difficult to engage in any type of fair negotiations when one of the parties has that kind of monopoly power . . . I think that is something that is going to continue getting attention, especially as we see more of these payers and PBMs continue to try to further consolidate."⁷⁴

Insular Nature of the PBM Industry

227. The insular nature of the PBM and pharmaceutical industry has provided PBM Defendants with ample opportunity for contact and communication with their competitors, as well as with Manufacturer Defendants, in order to devise and agree to the Insulin Pricing Scheme.

228. PBM Defendants routinely communicate through direct interaction with their competitors and manufacturers at trade associations and industry conferences.

229. Each year during the relevant time period, the main PBM trade association, the Pharmaceutical Care Management Association ("PCMA"), held several yearly conferences, including its Annual Meeting and its Business Forum conferences. All PBM Defendants are members of the PCMA and all Manufacturer Defendants are affiliate members of this organization. Every year, high-level representatives and corporate officers from both PBM Defendants and Manufacturer Defendants attended these conferences to

⁷³ *Id.*

⁷⁴ See <https://www.fiercehealthcare.com/payer/senate-hearing-puts-spotlight-debate-over-consolidation-pbm-market>.

meet in person and engage in discussions, including those in furtherance of the conspiracy alleged herein.

230. In fact, for at least the last six (6) years, all of the Manufacturer Defendants have been “Presidential Sponsors” to these PBM conferences.

231. Notably, many of the forums at these conferences are specifically advertised as offering opportunities for private, non-public communications. For example, as Presidential Sponsors of these conferences, Manufacturer Defendants each hosted “private meeting rooms” that offer “excellent opportunities for . . . one-on-one interactions between PBM and pharma executives.”

232. In addition, all PCMA members, affiliates and registered attendees of these conferences are invited to join PCMA-Connect, “an invitation-only LinkedIn Group and online networking community.” As PCMA members, PCMA-Connect provided PBM and Manufacturer Defendants with a year-round, non-public online forum to engage in private discussions in furtherance of the conspiracy alleged herein.

233. Communications between PBM Defendants are facilitated by the fluidity and frequency with which executives move from one PBM Defendant to another. Representative examples include:

- a. Mark Thierer worked as an executive at the PBM Medco (which became part of Express Scripts) until he became the CEO of OptumRx in 2016;
- b. Bill Wolfe was the President of the PBM Catalyst Rx (which became part of OptumRx) prior to becoming the President of Aetna Rx in 2015;
- c. Duane Barnes was the Vice President of Medco (which became part of Express Scripts) prior to becoming division President of Aetna Rx in 2006;

d. Everett Nevill was the division President of Aetna Rx before becoming Senior Vice President of Express Scripts of 2015;

e. Albert Thigpen was a Senior Vice President at CVS Caremark prior to becoming a Senior Vice President at OptumRx in 2011;

f. Harry Travis was the Chief Operating Officer at Medco (which became Express Scripts) before becoming a Vice President at Aetna Rx in 2008; and

g. Bill Kiefer was a Vice President of Express Scripts before becoming a Senior Vice President at OptumRx in 2015.

D. The Insulin Pricing Scheme

234. Leveraging their dominant market power, PBM Defendants have teamed up with Manufacturer Defendants to create the Insulin Pricing Scheme that permits them to extract exorbitant profits from the pharmaceutical distribution chain.

235. There are three interrelated components to this scheme: (1) Manufacturer Defendants have agreed with each other and with PBM Defendants to artificially inflate the reported price for diabetes medications; (2) Manufacturer Defendants have agreed to send payments back to PBMs for each unit sold; and (3) in exchange for (1) and (2), PBMs have agreed to give Manufacturer Defendants' diabetes medications preferred placement on PBM's standard formularies resulting in increased utilization of those products.

236. While this agreement greatly benefits both PBM and Manufacturer Defendants, it has severely damaged both Harris County and consumers in the insulin market.

Artificially Inflating the Reported Price and the Secret Payment Game

237. The Insulin Pricing Scheme begins with Manufacturer Defendants purposefully inflating the reported price of their diabetes medications in order to receive favorable formulary treatment by PBM Defendants.

238. In a transparent and competitive marketplace, drug manufacturers would set the prices of their drugs at levels that account for multiple competitive factors, including: the drug's ingredient cost, relative safety and efficacy profiles, the prices of available treatment alternatives and the total cost to the manufacturer of research and development for the drug entering the marketplace.

239. Here, however, the competing products at issue are the same drugs they were when initially released. And most of the drugs at issue have been on the market for 15-20 years. The clinical benefits of these medications have not changed.

240. Dr. Kasia Lipska, a Yale researcher and author of a 2018 study in the Journal of the American Medical Association on the cost of insulin, explained:

We're not even talking about rising prices for better products here. I want to make it clear that we're talking about rising prices for the same product . . . there's nothing that's changed about Humalog. It's the same insulin that's just gone up in price and now costs ten times more.⁷⁵

241. Nor have the production or research and development costs increased.

242. Thus, there must be another factor motivating these price increases.

243. The real reason Manufacturer Defendants have increased their reported prices is because of the Insulin Pricing Scheme.

244. PBM Defendants control the formularies that determine whether diabetics will use Eli Lilly's, Novo Nordisk's or Sanofi's products. Drug formularies identify which

⁷⁵ Natalie Shure, *The Insulin Racket*, available at <https://prospect.org/health/insulin-racket/>.

drugs payors will pay for and at what rate. Thus, preferred placement on a formulary increases a drug's utilization and the manufacturer makes more money.

245. Controlling the baseline national formularies gives PBM Defendants a crucial point of leverage over the system.

246. Given the asymmetry of information between payors and PBM Defendants and the costs associated with making formulary changes, most payors accept the baseline national formularies offered by the PBMs.

247. Because PBM Defendants have such a dominant market share, if they chose to exclude a particular diabetes medication from these formularies, or give it a non-preferred position, it could mean billions of dollars in profit loss for Manufacturer Defendants.

248. Olivier Brandicourt, Sanofi's Chief Executive Officer, stressed the continuing importance of maintaining a favorable formulary position: "if you look at the way [CVS Caremark] is organized in the U.S., they are covering about 30 million lives as a PBM . . . I think it's actually 34 million. 15 million are part of the national formulary and that's very strict, all right. So, [if we were excluded from their formulary] we wouldn't have access to those 15 million lives."⁷⁶

249. PBMs have the greatest leverage in negotiating with drug manufacturers for formulary placement when the manufacturers' drugs have similar efficacy and risk profiles, as is the case with the at issue diabetes medications. In such a scenario, in a competitive market, manufacturers would compete on *lower* reported prices for formulary placement.

⁷⁶ Bank Of America Merrill Lynch Global Health Conference, London, UK (Sept. 16, 2016), available: <http://edge.media-server.com/m/p/7neehd6y>.

250. The Insulin Pricing Scheme, however, does not operate in such a manner. Rather, Manufacturer Defendants have agreed with each other and PBM Defendants to raise their publicly reported prices, but largely maintain the net price by paying a significant portion of this price back to PBM Defendants.

251. In exchange for this price spread enlargement, during the relevant time period PBM Defendants granted Manufacturer Defendants' diabetes medications with the most elevated reported price and the highest manufacturer refund amount preferred formulary status.

252. This pricing disconnect creates what is, in effect, a massive slush fund derived from the difference between the reported and net prices. As discussed in greater detail next, PBM Defendants can use this "fund" to extract hidden profits from the other participants within the pharmaceutical distribution system—namely payors, consumers and pharmacies.

253. The scheme affords Manufacturer Defendants the ability to pay back to PBM Defendants a significant, yet undisclosed, portion of their reported prices in exchange for formulary placement—which garners Manufacturer Defendants greater revenues from sales to more people—without decreasing their profit margins.

254. Manufacturer and PBM Defendants also use the inflated price to earn hundreds of millions of dollars in additional tax breaks by basing their deductions for donated insulins on the inflated reported price.

255. Unfortunately for payors like Harris County, and consumers in the insulin market in general, this scheme artificially drives up the price paid for diabetes medications.

256. Thus, far from using their prodigious bargaining power to lower drug prices as they claim, PBM Defendants use their position to benefit both themselves and Manufacturer Defendants.

257. This Insulin Pricing Scheme is an extremely profitable enterprise for all Defendants, though deeply damaging to payors and consumers who shoulder the burden of the higher prices.

Defendants Admit to Artificially Inflating Price to Buy Formulary Position

258. Manufacturer Defendants have admitted that their price hikes are unrelated to any increase in clinical benefit, production costs or research and development.

259. Instead, the inflated price is part of the Insulin Pricing Scheme: Manufacturer Defendants have agreed with PBM Defendants to raise their reported prices while secretly refunding a portion of that price back to PBMs to buy formulary position.

260. On April 10, 2019, the United States House of Representatives Committee on Energy and Commerce held a hearing on Defendants' Insulin Pricing Scheme titled, "Priced Out Of A Lifesaving Drug: Getting Answers on the Rising Cost of Insulin."

261. Nearly all of Defendants testified at that hearing and each acknowledged before Congress that the price for insulin has increased exponentially in the past fifteen (15) years. Yet, none of the testifying Defendants claimed that the significant increase in the price of insulin was related to competitive factors such as increased costs or improved clinical benefit.

262. Rather, Defendants have admitted how they agreed to and did participate in the Insulin Pricing Scheme and that the rise in insulin prices was a direct result of the scheme.

263. For example, in explaining the company's increases to the reported price of its diabetes medications, Novo Nordisk directly admitted that "as the manufacturer, we do set the [reported] price and have full accountability for those increases." The statement continued on to explain that raising the reported price is necessary, "in order for [Novo Nordisk's] medicines to stay on [PBMs] preferred drug list or formulary."⁷⁷

264. At the April 2019 Congressional hearing Novo Nordisk's President, Doug Langa, elaborated on Novo Nordisk's and PBM Defendants' role in perpetuating the "perverse incentives" of the Insulin Pricing Scheme:

There is this perverse incentive and misaligned incentives (in the insulin pricing system) and this encouragement to keep [reported] prices high. And we've been participating in that system because the higher the [reported] price, the higher the rebate . . . There is a significant demand for rebates. We spend almost \$18 billion in rebates in 2018 . . . If we eliminate all the rebates . . . we would be in jeopardy of losing [our formulary] positions.⁷⁸

265. Eli Lilly, too, has admitted that it raises reported prices as a *quid pro quo* for formulary positions: "The reason drug makers sharply raise reported prices without a corresponding increase in net price is that PBMs demand higher rebates in exchange for including the drug on their preferred-drug lists."⁷⁹

266. At the April 2019 Congressional hearing, Mike Mason, Senior Vice President of Eli Lilly testified:

Seventy-five percent of our [reported] price is paid for rebates and discounts to secure [formulary position] . . . \$210 of a vial of Humalog is paid for discounts and rebates. . . We have to provide rebates [to PBMs] in order to provide and compete for [formulary position].

⁷⁷ Novo Nordisk Press Release, <http://press.novonordisk-us.com/leadership-perspectives?item=1>.

⁷⁸ *Priced Out Of A Lifesaving Drug: Getting Answer On The Rising Cost Of Insulin*, Hearing Before the Subcomm. on Energy and Commerce, (April 10, 2019).

⁷⁹ Denise Roland & Peter Loftus, *Middlemen Fuel Insulin Price Rise*, Wall St. J., at B1.

267. Sanofi has also conceded its participation in the Insulin Pricing Scheme:

[S]ince 2014, we have increased the level of rebates granted for Lantus in order to maintain favorable formulary positions.⁸⁰

268. When testifying at the April 2019 Congressional hearing, Kathleen Tregoning, Executive Vice President for External Affairs of Sanofi, testified:

The rebates are how the system has evolved. The rebates are part of the negotiation to secure formulary placement . . . I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices . . .⁸¹

269. PBM Defendants also admitted at the April 2019 Congressional hearing that they grant preferred, or even exclusive, formulary position because of higher rebates paid by Manufacturer Defendants. For example, Amy Bricker, Senior Vice President of Express Scripts, when asked to explain why Express Scripts did not grant an insulin with a lower reported price preferred formulary status, answered, “[m]anufacturers do give higher [rebates] for exclusive [formulary] position . . .”⁸²

Data Corroborates Defendants’ Admission To The Insulin Pricing Scheme

270. The data corroborates Defendants’ admissions that they have inflated the reported prices and paid back to PBM Defendants larger and larger amounts in exchange for PBM Defendants granting Manufacturer Defendants’ diabetes medications preferred formulary status.

271. Over the last fifteen (15) years, while Manufacturer Defendant’s reported price has risen dramatically, the net price realized by these firms has not.

⁸⁰ Sanofi, Annual Report (Form 20-F) (Dec. 31, 2016).

⁸¹ *Supra* note 78.

⁸² *Id.*

272. Figures 12 and 13 illustrate how Novo Nordisk's reported price has significantly diverged from its net price.

Figure 12: Net prices versus reported prices of NovoLog vial
NovoLog® Vial

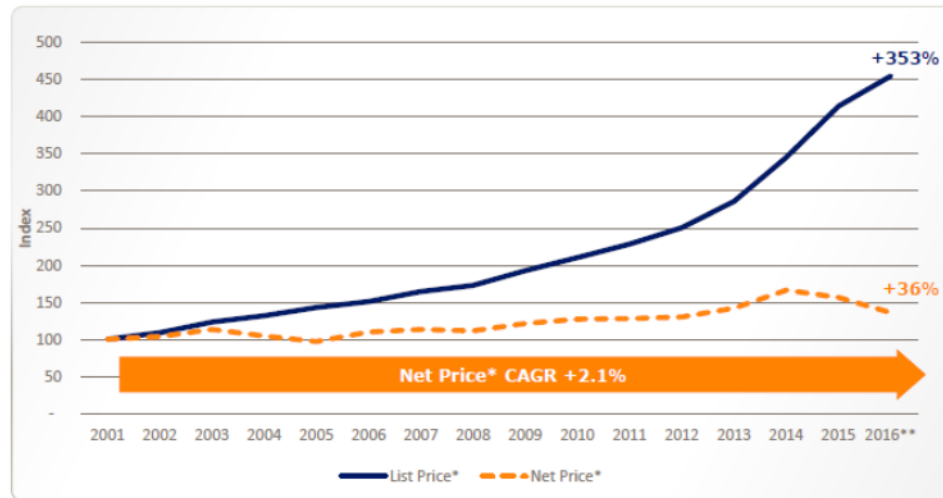
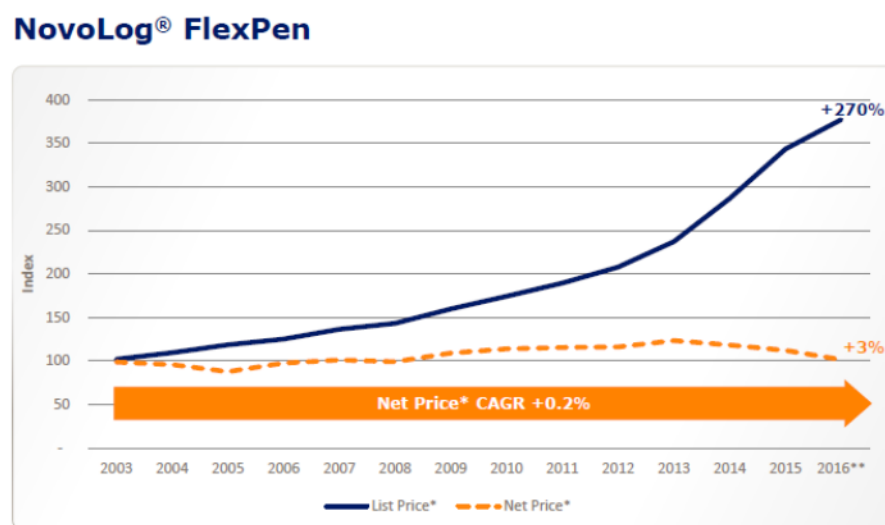
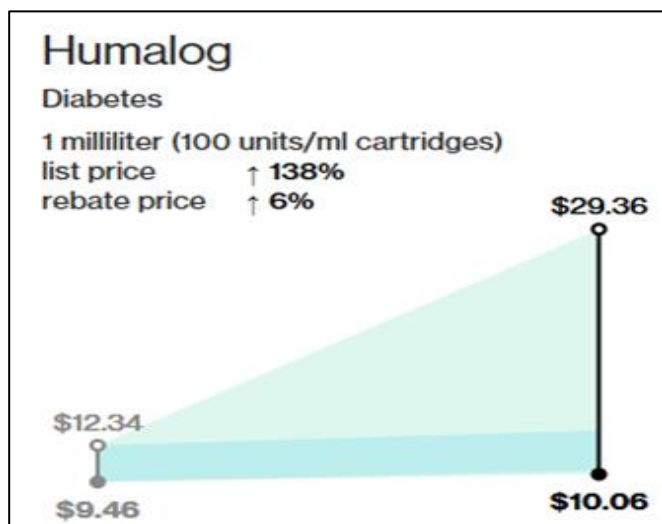


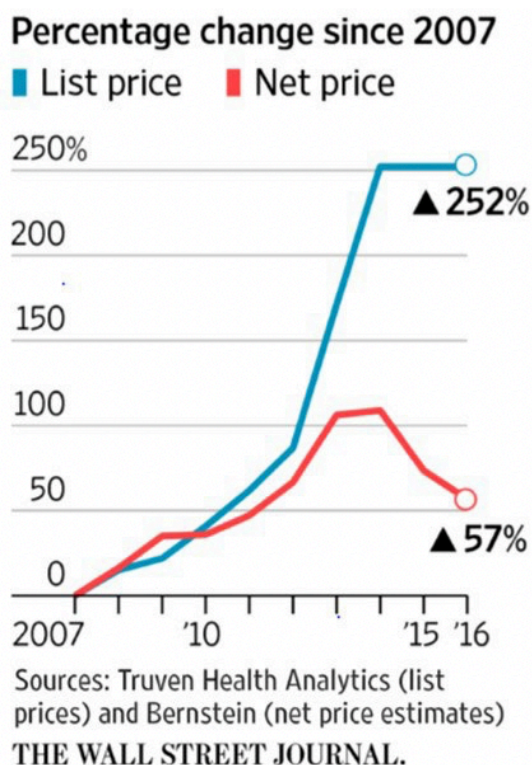
Figure 13: Net prices versus reported prices of NovoLog pens
NovoLog® FlexPen



273. Figure 14 shows the widening gap between Eli Lilly's reported price and the net price of Humalog.

Figure 14: Net prices versus reported prices of Eli Lilly's Humalog

274. Sanofi's manipulation of its spreads is visible in Figure 15:

Figure 15: Sanofi's net prices versus reported prices of Lantus

275. Thus, Defendants admit—and the data corroborates—their respective roles in the Insulin Pricing Scheme.

PBM Profit Off the Insulin Pricing Scheme

276. PBM Defendants and Manufacturer Defendants have conspired to artificially inflate the reported price of diabetes medications to exploit profits from payors like Harris County.

277. For Manufacturer Defendants, their artificially inflated prices allow them to make large secret payments back to PBM Defendants in order to buy formulary position, which leads to increased sales and profits. And, during the relevant time period, PBM Defendants granted national formulary position to each at-issue drug in exchange for Manufacturer Defendants' large payments and inflated prices.

278. PBM Defendants profit off the Insulin Pricing Scheme by: (1) pocketing significant portions of the payments made by Manufacturer Defendants ("Secret Payment Game"); (2) charging payors, such as Harris County, based on the inflated prices and then reimbursing pharmacies a lower price for the same product ("Pharmacy Spread") and (3) using the inflated price to increase their margins on diabetes medications sold through their own mail order pharmacies.

279. With respect to (1), the Secret Payment Game, the rate of increase in payments by Manufacturer Defendants has accelerated to represent more than half of the list price of diabetes medications.⁸³

280. When PBMs contract with payors, the contract allows the PBM to keep all or at least some of these payments, rather than pass them along to the payor. In fact, a recent

⁸³ Langreth R, Keller M, Cannon C., *Decoding big pharma's secret drug pricing practices*, Bloomberg, 29 June 2016. Available from <https://www.bloomberg.com/graphics/2016-drug-prices/>.

study showed that most employers report that they do not receive the total share of the rebates that PBMs claim to pass on to them.⁸⁴

281. Since payments are kept confidential between Manufacturer Defendants and PBM Defendants, payors are unable to determine how much PBMs are keeping for themselves.

282. Over time, payors, including Harris County, have secured contract provisions guaranteeing them all or some portion of the “rebates” paid by drug manufacturers to PBMs. But—critically—“rebates” are only a portion of the total secret payments paid.

283. In this regard, PBM and Manufacturer Defendants have created a “hide-the-ball” system where the consideration exchanged between them (and not shared with payors) is labeled and relabeled. As more payors moved to contracts that required PBMs to pass a majority of the manufacturer “rebates” through to the payor, PBMs have begun relabeling these payments in order to keep a more substantial portion of this money. Payments once known as “rebates” are now called administrative fees, volume discounts, service fees, price or margin guarantees or other industry jargon terms designed to obfuscate and distract from the substantial sums being secretly exchanged.

284. And the secret payments are indeed substantial. A recent heavily redacted complaint filed by Defendant Express Scripts revealed that *Express Scripts now retains*

⁸⁴ Elizabeth Seeley and Aaron S. Kesselheim, *Pharmacy Benefit Managers: Practices Controversies, and What Lies Ahead*, *The Commonwealth Fund*, March 26, 2019, available at <https://www.commonwealthfund.org/publications/issue-briefs/2019/mar/pharmacy-benefit-managers-practices-controversies-what-lies-ahead>.

*up to 13 times more in “administrative fees” than it passes through to payors in formulary rebates.*⁸⁵

285. With respect to the second way that PBM Defendants profit off the Insulin Pricing Scheme—the Pharmacy Spread—PBM Defendants decide which pharmacies are included in a prescription drug plan and how much they will reimburse pharmacies for each drug dispensed.

286. PBM Defendants do not specifically disclose to the payor how much the PBM is reimbursing the pharmacies for the drugs dispensed or vice versa.

287. The price that the payor pays for diabetes medications is directly tied to the artificially inflated reported price, while the price the pharmacy is reimbursed for the drug often is not.

288. This allows PBM Defendants to charge the payor significantly more than what the PBM is reimbursing the pharmacy for the same drug and the PBM pockets the difference.

289. Spread pricing, like secret payment negotiation, happens behind closed doors. There is no transparency, no commitment from PBM Defendants to take into account the cost effectiveness of a drug and no communication with the payors to let them know if they are getting a fair deal.

290. While some spread pricing can be expected even in a fair market, the opacity of the profit stream of the Insulin Pricing Scheme masks the allegedly low costs PBM Defendants tout to payors to get them to sign up and demonstrates the strong financial incentive PBMs have to drive up the reported price.

⁸⁵ *Express Scripts, Inc., et al. v. kaleo, Inc.*, Case No. 4:17-cv-01520-RLW (E.D.Mo 2017).

291. With respect to the third way PBMs profit off the Insulin Pricing Scheme—PBM Defendants all operate their own highly profitable mail order pharmacies. The higher the price that PBM Defendants are able to get their customers, such as payors like Harris County, to pay for diabetes medications, the higher the profit PBM Defendants realize through their own mail order pharmacies.

E. The Insulin Pricing Scheme Deceived and Harmed Harris County and the Insulin Market

292. Defendants' Insulin Pricing Scheme has deceived Harris County and it has cost the County millions of dollars.

293. The Harris County government serves its almost five (5) million residents providing public safety, emergency management and health services just to name a few of its vital roles. As more federal and state responsibilities are mandated to local government, Harris County has to meet a growing list of demands on a limited budget. Consequently, any significant increase in spending can have a severe detrimental effect on Harris County's overall budget and, in turn, negatively impact its ability to provide necessary services to the community or force the County to raise taxes to compensate for the losses.

294. As a large government employer, Harris County provides health benefits to approximately 38,000 Beneficiaries.

295. One of the benefits that Harris County offers its Beneficiaries is paying a significant portion of the cost of their healthcare.

296. Harris County is what is known as a self-funded health plan—meaning Harris County provides health benefits using its own funds, including funds contributed by its Beneficiaries. As part of this health plan, Harris County subsidizes its Beneficiaries' prescription drug purchases.

297. Harris County also spends millions of dollars a year purchasing pharmaceutical drugs, including the at issue diabetes medications, that are administered to inmates in the Harris County jails.

298. As detailed in Appendix A, as part of its pharmaceutical drug spend, Harris County spends millions of dollars every year on the at issue drugs.

299. To administer its pharmaceutical drug purchases, Harris County relies on PBMs, for the alleged purposes of limiting administrative burden and controlling pharmaceutical drugs costs.

300. At different periods during the relevant time, Defendants Aetna Rx, CVS Caremark, OptumRx and Express Scripts provided PBM services to Plaintiff Harris County.

301. At different periods during the relevant time, Harris County utilized each PBM Defendant's formularies with respect to the at issue drugs.

302. PBM Defendants set the price by which Harris County paid for the drugs utilized by Harris County's Beneficiaries, including the at issue diabetes medications. PBM Defendants also receive payments made by Harris County for the at issue diabetes medications, and, in turn, reimburse the pharmacies that dispensed these drugs (often at a lower rate than the amount paid by Harris County).

303. Unfortunately, these PBMs did not live up to their promise of lowering the cost of Harris County's diabetes medication purchases. To the contrary, as a direct result of Defendants' Insulin Pricing Scheme, the amount that Harris County pays for diabetes medications has increased significantly in the last ten (10) years.

Defendants Deceived Harris County

304. Defendants deceived Harris County into paying significantly inflated prices for diabetes medications.

305. PBM Defendants purposefully, consistently and routinely misrepresented that they negotiate with Manufacturer Defendants for the benefit of payors, such as Harris County, and to save payors money. PBM Defendants specifically made these misrepresentations to induce reliance by payors, including Harris County.

306. Each PBM Defendant purposefully, consistently and routinely misrepresented that it uses its market power and expertise to maximize savings for payors, including Harris County. PBM Defendants specifically made these misrepresentations to induce reliance by payors, including Harris County.

307. Each PBM Defendant purposefully, consistently and routinely misrepresented that it designs pharmaceutical plans and constructs formularies for the purposes of promoting client health and safety, including the health and safety of Harris County's Beneficiaries. PBM Defendants specifically made these misrepresentations to induce reliance by payors, including Harris County.

308. For example, throughout the relevant time period, Defendant CVS Caremark has consistently stated that its design and administration of formularies are "aimed at reducing the costs and improving the safety, effectiveness and convenience of prescription drugs."⁸⁶

309. CVS Caremark has also maintained that "[w]e utilize an independent panel of doctors, pharmacists and other medical experts. . . to review and approve the selection

⁸⁶ See, e.g. CVS Caremark, Annual Report (Form 10-K) (Dec. 31, 2007); CVS Caremark, Annual Report (Form 10-K) (Dec. 31, 2010).

of drugs that meet our high standards of safety and efficacy for inclusion on one of our template formularies. Our formularies . . . help[] to drive the lowest net cost for our clients . . .”⁸⁷

310. Likewise, Defendant Express Scripts has consistently represented that it “works with clients, manufacturers, pharmacists and physicians to increase efficiency in the drug distribution chain, to manage costs in the pharmacy benefit chain and to improve members’ health outcomes.”⁸⁸

311. Express Scripts has further represented, at all times relevant hereto, that “[i]n making formulary recommendations, [our Pharmacy & Therapeutics Committee] considers the drug’s safety and efficacy, without any information on or consideration of the cost of the drug, including any discount or rebate arrangement we might negotiate with the manufacturer. . . We fully comply with the P&T Committee’s clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of safety and efficacy.”⁸⁹

312. Similarly, throughout the relevant time period, Defendant OptumRx has consistently stated, that OptumRx’s “rebate contracting and formulary management . . . assist customers in achieving a low-cost, high-quality pharmacy benefit.”⁹⁰

313. OptumRx further maintains, that it “promotes lower costs by using formulary programs to produce better unit costs, encouraging consumers to use drugs that

⁸⁷ CVS Caremark, Annual Report (Form 10-K) (Dec. 31, 2017).

⁸⁸ Express Scripts, Annual Report (Form 10-K) (Dec. 31, 2013).

⁸⁹ Express Scripts, Annual Report (Form 10-K) (Dec. 31, 2017).

⁹⁰ OptumRx, Annual Report (Form 10-K) (Dec. 31, 2010).

offer improved value” and that OptumRx’s formularies are selected for payors based on “their safety, cost and effectiveness.”⁹¹

314. In addition to these general false representations, purposefully made with the intent to induce reliance, PBM Defendants further and specifically also misrepresented that the payments they receive from Manufacturer Defendants lower the price of the at issue diabetes medications and that the preferred formulary status of these medications reflects these drugs’ safety, efficacy and cost-effectiveness. These misrepresentations were likewise made with the intent to induce reliance.

315. For example, when testifying under oath before Congress earlier this year on the rising price of insulins, Senior Vice President Amy Bricker of Express Scripts testified that “Express Scripts remains committed to . . . patients with diabetes and creating affordable access to their medications.”⁹²

316. Later in the sworn testimony, Express Scripts’ Vice President added, “I have no idea why the prices [for insulin] are so high, none of it is the fault of rebates.”⁹³

317. CVS Caremark’s Chief Policy and External Affairs Officer similarly testified during the April 2019 hearings that, CVS Caremark “has taken a number of steps to address the impact of insulin price increases. We negotiate the best possible discounts off the manufacturers’ price on behalf of employers, unions, government programs, and beneficiaries that we serve.”⁹⁴

⁹¹ OptumRx, Annual Report (Form 10-K) (Dec. 31, 2017); *see also* https://www.optumrx.com/content/dam/openenrollment/pdfs/som/Formulary%20Booklet%20Select_Standard_010119_final.pdf.pdf.

⁹² *See supra* note 78.

⁹³ *Id.*

⁹⁴ *Id.*

318. Chief Medical Officer of OptumRx, testified that for “insulin products . . . we negotiate with brand manufacturers to obtain significant discounts off list prices on behalf of our customers.”⁹⁵

319. Not only have PBM Defendants intentionally misrepresented that they use their market power to save payors money, they also have specifically, knowingly and falsely disavowed that their conduct drives prices higher.

320. For example, on an Express Scripts’ earnings call in February 2017, CEO Tim Wentworth stated, “Drugmakers set prices, and we exist to bring those prices down.” Larry Merlo, head of CVS Caremark sounded a similar refrain six (6) days earlier, “Any suggestion that PBMs are causing prices to rise is simply erroneous.”⁹⁶

321. Later that same year, Express Scripts’ Wentworth went on CBS News to again argue that PBMs play no role in rising drug prices, stating that PBMs work on behalf of payors to “negotiate with drug companies to get the prices down.”⁹⁷

322. During the April 2019 Congressional hearings, when asked if PBM-negotiated rebates and discounts were causing the insulin price to increase, OptumRx’s Chief Medical Officer answered, “we can’t see a correlation when rebates raise list prices.”⁹⁸

⁹⁵ *Id.*

⁹⁶ Lynn R. Webster, *Who is to Blame for Skyrocketing Drug Prices*, The Hill, July 27, 2017, available at <https://thehill.com/blogs/pundits-blog/healthcare/344115-who-is-to-blame-for-skyrocketing-drug-prices>.

⁹⁷ *See e.g.* Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices, CBS News, February 7, 2017, available at <https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbm-rising-drug-prices-mylan-epipen-heather-bresh/>; *see also* Express Scripts, Annual Report (Form 10-K) (Dec. 31, 2017).

⁹⁸ *See supra* note 78.

323. Throughout the relevant time period, PBM Defendants have also knowingly, consistently and falsely represented that they are transparent about the payments they receive from Manufacturer Defendants.

324. PBM Defendants' have represented to Harris County, the public and to Congress that they are passing along all "rebates" to plans when in reality "rebates" are today a small fraction of the total payments PBMs receive from manufacturers in exchange for formulary placement and driving utilization. In fact, as stated previously, PBM Defendants retain up to thirteen (13) times more in "administrative fees" than the formulary rebates they pass through to their clients, like Harris County.⁹⁹

325. Despite this, in a 2017 CBS News interview, Express Scripts' CEO, represented, among other things, that PBMs' rebate and payment structures are "absolutely transparent" and that clients of PBMs, such as the Harris County, "know exactly how the dollars flow" with respect to the payments PBMs receive from drug manufacturers.

326. When testifying before Congress earlier this year, Amy Bricker, Senior Vice President of Defendant Express Scripts had the following exchange with Representative John Sarbanes of Maryland regarding the transparency (and lack thereof) of the PBM Secret Payment Game:

Ms. Bricker. The rebate system is 100 percent transparent to the plan sponsors and the customers that we service. To the people that hire us, employers of America, the government, health plans, what we negotiate for them is transparent to them. . . [However] the reason I'm able to get the discounts that I can from the manufacturer is because it's confidential [to the public].

Mr. Sarbanes. What about if we made it completely transparent? Who would be for that?

⁹⁹ *Express Scripts, Inc., et al. v. kaleo, Inc.*, Case No. 4:17-cv-01520-RLW (E.D.Mo 2017).

Ms. Bricker. Absolutely not . . . it will hurt the consumer.

Mr. Sarbanes. I don't buy it.

Ms. Bricker – prices will be held high.

Mr. Sarbanes. I am not buying it. I think a system has been built that allows for gaming to go on and you have all got your talking points. Ms. Tregoning [of Sanofi], you have said you want to guarantee patient access and affordability at least ten times, which is great, but there is a collaboration going on here . . . the system is working for both of you at the expense of the patient. Now I reserve most of my frustration for the moment in this setting for the PBMs, because I think the lack of transparency is allowing for a lot of manipulation. I think the rebate system is totally screwed up, that without transparency there is opportunity for a lot of hocus-pocus to go on with the rebates. Because the list price ends up being unreal in certain ways except to the extent that it leaves certain patients holding the bag, then the rebate is negotiated, but we don't know exactly what happens when the rebate is exchanged in terms of who ultimately benefits from that. And I think we need more transparency and I do not buy the argument that the patient is going to be worse off, the consumer is going to be worse off if we have absolute transparency . . . I know when you started out, I understand what the mission was originally with the PBMs . . . But now things have gotten out of control. You are too big and the lack of transparency allows you to manipulate the system at the expense of the patients. So I don't buy the argument that the patient and consumer is going to get hurt if we have absolute transparency.¹⁰⁰

327. In 2011, OptumRx's President echoed Express Scripts' representations on transparency: "We want our clients to fully understand our pricing structure . . . [e]veryday we strive to show our commitment to our clients, and one element of that commitment is to be open and honest about our pricing structure."¹⁰¹

328. Throughout the relevant time period, PBM Defendants also knowingly, consistently and repeatedly made representations directly to Harris County that mirrored these false public statements and sworn testimony. Representative examples include:

¹⁰⁰ See *supra* note 78.

¹⁰¹ <https://www.unitedhealthgroup.com/newsroom/2011/0913tipps.html>.

a. In July 2003, Harris County received written solicitation material in which Aetna Rx represented that its national formularies promote cost effective drugs and that preferred formulary positions were selected based on quality, safety and efficacy;

b. On July 31 2008, Harris County received written solicitation material in which Aetna Rx represented that its pharmacy benefit services would lower the cost of Harris County's prescription drugs through "aggressive rebates [and] discounts" negotiated from drug manufacturers and that Aetna Rx's "over thirty years of pharmacy benefit management experience" allow it to construct formularies that control rising brand name drug costs;

c. On June 19, 2012, Harris County received written solicitation material in which Aetna Rx, working with CVS Caremark, represented that its pharmacy benefit management services drove "better health and cost outcomes," produced a potential savings of millions of dollars and with respect to Harris County's diabetic beneficiaries in particular, would save Harris County hundreds of thousands of dollars annually;

d. In August 2016, OptumRx submitted written material to Harris County that represented that the payments it received from drug manufacturers and its management of its national formularies lowered the cost of prescription medications; and

e. In 2018, Express Scripts made oral representations to Harris County that the payments it received from drug manufacturers were for the benefit of Harris County and that its formulary management lowered the cost of prescription drugs.

329. These direct misrepresentations to Harris County were also made with the specific intent to induce reliance by Harris County.

330. Further, Manufacturer and PBM Defendants have continuously misrepresented—through publishing their reported prices and basing the price Harris County paid for diabetes medications on their reported prices—that the reported price of their diabetes medications bears a reasonable relationship to the net price realized by Defendants and results from competitive market forces.

331. Plaintiff Harris County has now discovered that each of these representations are patently false. Harris County has learned that, in fact, PBM Defendants' plan design, formulary construction and Defendants' inflated reported prices are all integral parts of the Insulin Pricing Scheme targeted at maximizing Defendants' profits at the expense of Harris County.

332. Defendants knew that these representations were false when they made them. Defendants intentionally made these false representations so that Harris County would rely upon them.

333. At all times during the relevant period, PBM Defendants knew that its formulary positions were not granted for the purpose of promoting the health and safety of diabetics, including Harris County's Beneficiaries, but rather were given to Manufacturer Defendants in exchange for artificially inflated prices and payments. PBM Defendants affirmatively withheld this truth from Harris County.

334. At all times during the relevant period, PBM Defendants knew they were not transparent with payors, including Harris County, regarding the payments they received from Manufacturer Defendants, but rather were concealing these payments in order to

hide the significant revenue they generated. PBM Defendants affirmatively withheld this truth from Harris County.

335. At all times during the relevant period, Manufacturer Defendants knew that its reported prices did not result from competitive market forces, but rather were artificially inflated in coordination with their competitors for the purpose of maximizing profits. Manufacturer Defendants affirmatively withheld this truth from Harris County.

336. Defendants concealed the falsity of these representations by closely guarding their pricing structures, agreements and sales figures.

337. Manufacturer Defendants do not disclose to payors or the public the net prices or rebates or other payments they offer to and pay PBM Defendants.

338. PBM Defendants do not disclose the details of their agreements with drug manufacturers or the payments they receive from them—nor do they disclose the details related to their agreements with payors and pharmacies.

339. PBM Defendants have gone as far as suing governmental entities to block the release of details on their pricing agreements with manufacturers and pharmacies.¹⁰²

340. Even when audited by payors, PBM Defendants often still refuse to disclose their agreements with manufacturers and pharmacies, relying on overly broad confidential agreements, claims of trade secrets and other unnecessary restrictions.

341. In a previous lawsuit involving the manipulation of drug pricing spreads, evidence came forth explicitly demonstrating this deceit:

Because these PBMs benefited from the increased spreads perpetuated by the Scheme, Plaintiffs argue that they had no incentive to inform [third party payors] of the inflated AWP, let alone fiercely compete to mitigate any

¹⁰² Catherine Candisky, “CVS Sues State To Block Release of Report On Its Drug Pricing,” The Columbus Dispatch July 16, 2018, available at <https://gatehousenews.com/sideeffects/cvs-sues-state-block-release-report-drug-pricing/site/dispatch.com/>

damage. As proof, Plaintiffs quote an April 26, 2002 internal [PBM] e-mail . . . that states that “the AWP increases being pushed through by First Data Bank [are] having a very favorable impact on our mail margins.” The e-mail goes on to state, “Our clients (payors) will not be sympathetic to our financial situation since we [will have benefited] from the AWP increase in the mail and they hired us to control drug trend.” The e-mail includes a handwritten note, in response, “Let’s put a lid on it and not make it a big deal.”¹⁰³

342. Defendants intended the Insulin Pricing Scheme to induce reliance from payors, including Harris County, and cause unlawful and excessive payments for the products at issue.

343. The Insulin Pricing Scheme enabled Manufacturer Defendants to offer something of value to the PBM Defendants—inflated prices and payments—in exchange for preferred formulary status. Manufacturer Defendants knew that these prices were artificially inflated and intentionally did not disclose this to Harris County or the public.

344. PBM Defendants were able to use the inflated prices to create significant profit streams from the Secret Payment Game, the Pharmacy Spread and their own mail order pharmacies.

345. Without the Insulin Pricing Scheme and its secret payment and pricing system, Defendants would have been forced to compete for market share in the way competitors do in a healthy market: by offering lower actual prices that are available and transparent to the participants in the market.

346. PBM Defendants were able to use the inflated reported prices as a basis for the price Harris County paid for the at issue drugs because Harris County relied on Defendants’ misrepresentations and believed that the price it paid was reasonable and resulted from competitive market forces. Defendants knew that these prices did not result

¹⁰³ *New England Carpenters Health Benefits Fund v. First Data Bank, Inc.*, 248 F.R.D. 363, 367 (D. Mass 2008) (internal citations omitted).

from competitive market forces, but were the result of the Insulin Pricing Scheme, and failed to disclose this to Harris County.

347. At all times relevant hereto, as a result of its reliance on Defendants' misrepresentations, Harris County paid for diabetes medications at artificially inflated prices to its significant detriment.

Defendants' Insulin Pricing Scheme Damaged Harris County

348. Harris County was and is damaged as a direct result of Defendants' Insulin Pricing Scheme.

349. Harris County spends millions of dollars each year on the at issue drugs.¹⁰⁴ The price that Harris County paid for these drugs is directly tied to Manufacturer Defendants' reported price. Thus, because Defendants' Insulin Pricing Scheme caused the reported prices to fraudulently and substantially increase, Defendants' pattern of fraudulent conduct directly and proximately caused Harris County to substantially overpay for diabetes medications.

350. The amount it has overpaid is the difference between the price that Harris County paid for these drugs and what it would have paid absent the Insulin Pricing Scheme. Factors to be considered include: the cost to manufacture the at issue drugs; a reasonable profit margin; the payments that Manufacturer Defendants made to PBM Defendants that were not passed through to Harris County; the amount that PBM Defendants pocketed from the fraudulent Pharmacy Spread; and PBM Defendants' additional undisclosed profit margins on diabetes medications purchased for and dispensed through their own mail order pharmacies.

¹⁰⁴ See Appendix A.

Defendants' Insulin Pricing Scheme has Damaged Competition and Consumers

351. Defendants' Insulin Pricing Scheme has also harmed competition and other consumers within the insulin market by anticompetitively and artificially inflating the price of insulin.

352. As a result of years of market concentration, as detailed above, PBM Defendants have a dominant market share in controlling the pricing and administration of the prescription drug market in Texas. To further exacerbate this market saturation, PBM Defendants carve up the market geographically, effectively not competing in certain regions of the country.¹⁰⁵ Amid such concentration, consumers in the insulin market, such as payors like Harris County, have little ability to select the best PBM on price or quality.

353. Equally concentrated is the insulin product market, with Manufacturer Defendants representing 99% of all insulin products sold.¹⁰⁶

354. Manufacturer Defendants have taken numerous steps to ensure that they maintain their dominant market share.

355. For example, Manufacturer Defendants engage in a practice known as “evergreening.” In a competitive drug market, manufacturers are granted a short period of market exclusivity prior to the expiration of their patent in order to increase profits to offset the substantial cost of bringing a new drug to the market. Once the patent expires, generics (in the case of insulin, biosimilars) enter the market at a substantially lower price.

356. Here, however, Manufacturer Defendants have engaged in the repatenting tactic called “evergreening,” in which a series of extra patents on incremental variations of

¹⁰⁵ David Dayen, *The Hidden Monopolies That Raise Drug Prices*, The American Prospect, Spring 2017, available at <https://prospect.org/health/hidden-monopolies-raise-drug-prices/>.

¹⁰⁶ Beran, *supra* note 53.

the original drug are sought solely for the purposes of extending the life of a patent after initial expiration. Defendant Sanofi, for example, has applied for sixty-nine (69) different patents on Lantus in the U.S. *after* the drug was approved in 2000.¹⁰⁷ Evergreening prevents generics/biosimilars from entering the market, even though the patented “improvements” are often inconsequential and do not produce better clinical results.

357. In addition to “evergreening,” Manufacturer Defendants have also engaged in “pay for delay,” where a generic/biosimilar manufacturer acknowledges the original patent of a pharmaceutical company and agrees to refrain from marketing its product for a specific period of time in return for payment.

358. One example of this occurred a few years ago when the drug company Merck announced plans to sell a biosimilar version of Sanofi’s Lantus. Sanofi sued, and eventually Merck announced that it was no longer pursuing its biosimilar due to payments from Sanofi to stay off the market.

359. As a result of their “evergreening” and “pay for delay” strategies, Manufacturer Defendants have eliminated competition for their insulins in order to maintain their dominant control over the U.S. insulin market.

360. Because of the market domination of both PBM Defendants and Manufacturer Defendants, consumers in this market, including payors, often have little or no choice as to which insulin drugs that they are able to purchase.

361. The insulins that are available to the consumer are directly determined by which insulin drugs PBM Defendants place on their formularies. And rather than allowing

¹⁰⁷ I-MAK Report, Lantus (Insulin Glargine) Overpatented, Overpriced, October 2018, available at: <http://www.i-mak.org/wp-content/uploads/2018/10/I-MAK-Lantus-Report-2018-10-30F.pdf>

competition and lower actual prices determine which insulins receive preferred status, PBM Defendants have agreed to grant formulary positions to Manufacturer Defendants based on which drug's price is the most inflated and which manufacturer makes the largest payments to them.

362. Thus, consumers in the insulin market are left with no reasonable substitutes—Manufacturer Defendants make nearly all of the insulin on the market and agreed in lockstep to increase the prices of these insulins. And PBM Defendants control which insulin products are available to consumers.

363. Consequently, consumers in this market, such as Harris County, are stuck in the Insulin Pricing Scheme, forced to pay the skyrocketing prices of Manufacturer Defendants' insulins.

V. TOLLING OF STATUTE OF LIMITATIONS

364. Plaintiff Harris County, as a county government, is a political subdivision of the State of Texas. Thus, pursuant to the common law and TEX. CIV. PRAC. & REM CODE 16.061, Harris County is not subject to any applicable statute of limitations.

365. Even assuming, *arguendo*, that Harris County was subject to applicable statutes of limitations, in the alternative Harris County asserts that it diligently pursued and investigated the claims asserted in this Complaint. Through no fault of its own, Harris County did not receive inquiry notice nor learn of the factual basis for its claims in this Complaint and the injuries suffered therefrom until recently. Consequently, the following tolling doctrines apply.

A. Discovery Rule Tolling

366. Harris County had no way of knowing about the scheme and deception with respect to Insulin Pricing Scheme.

367. As discussed above, PBM and Manufacturer Defendants refused to disclose the net prices of diabetes medications realized by Defendants, the details of the Defendants' negotiations and payments between each other or their pricing structures and agreements—labeling them trade secrets and protecting them with confidentiality agreements. Each Defendant group also affirmatively blamed the other for the price increase described herein, both during their congressional testimonies and through the media. Hence, a reasonable plaintiff and consumer could not discover the truth.

368. Within the period of any applicable statutes of limitation, Harris County could not have discovered, through the exercise of reasonable diligence, that Defendants were concealing the conduct complained of herein.

369. Harris County did not discover, and did not know of facts that would have caused a reasonable person to suspect, that Defendants were engaged in the Insulin Pricing Scheme, nor would a reasonable and diligent investigation have disclosed the true facts.

370. Even today, lack of transparency in the pricing of diabetes medications and the arrangements, relationships and agreements between and among Manufacturer Defendants and PBM Defendants that result from the Insulin Pricing Scheme continue to hide Defendants' unlawful conduct from Harris County.

371. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule with respect to claims identified herein.

B. Fraudulent Concealment Tolling

372. As detailed above, all applicable statutes of limitation have also been tolled by the Defendants' knowing and active fraudulent concealment and denial of the facts alleged herein throughout the time period relevant to this action.

C. Estoppel

373. Defendants were under a continuous duty to disclose to Harris County the true character, quality and nature of the reported prices upon which their payments for diabetes medications were based, and the true nature of the services being provided.

374. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

D. Continuing Violations

375. All applicable statutes of limitations are also tolled because Defendants' fraudulent activities have not ceased and still continue to this day and thus any causes of action are not complete and do not accrue until the tortious and anticompetitive acts have ceased.

VI. CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

**Violations of the Racketeer Influenced and Corrupt Organizations Act
("RICO"), 18 U.S.C. § 1962(c)
(Against Eli Lilly and All PBM Defendants)**

376. Plaintiff Harris County re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

377. This cause of action is brought by Plaintiff Harris County against Defendants Eli Lilly, Express Scripts, CVS Caremark, OptumRx and Aetna Rx for violations of 18 U.S.C. § 1962(c).

378. Defendants Eli Lilly, Express Scripts, CVS Caremark, OptumRx and Aetna Rx are (a) culpable "persons" who (b) willfully and knowingly (c) committed and conspired to the commission of mail and wire fraud (d) through a "pattern" (e) involving an "association in fact," (f) the results of which had an effect on interstate commerce.

A. Defendants are Culpable “Persons” Under RICO.

379. Defendants Eli Lilly, Express Scripts, CVS Caremark, OptumRx and Aetna Rx, separately, are “persons” as that term is defined in 18 U.S.C. § 1961(3) because each is capable of holding a legal or beneficial interest in property.

380. Each one of Defendants Eli Lilly, Express Scripts, CVS Caremark, OptumRx and Aetna Rx are separate entities and “persons” that are distinct from the RICO enterprises alleged below.

B. Eli Lilly-PBM RICO Enterprises

381. For the purposes of this claim, the RICO enterprises are four separate associations-in-fact consisting of one of each of the PBM Defendants that administers purchases of Eli Lilly’s Humulin N, Humulin R, Humalog, Trulicity and Basaglar, including those entities’ directors, employees, and agents, and Eli Lilly, including its directors, employees and agents: (1) the Eli Lilly-CVS Caremark association-in-fact enterprise; (2) the Eli Lilly-Express Scripts association-in-fact enterprise; (3) the Eli Lilly-OptumRx association-in-fact enterprise; and (4) the Eli Lilly-Aetna Rx association-in-fact enterprise (collectively, “Eli Lilly-PBM Enterprises”).

382. Each Eli Lilly-PBM Enterprise is a separate ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common and/or shared purposes of manufacturing, selling, facilitating the purchase of and profiting from the sale of Eli Lilly’s Humulin N, Humulin R, Humalog, Trulicity and Basaglar to the public and to Plaintiff Harris County.

383. With respect to the Insulin Pricing Scheme, each Eli Lilly-PBM Enterprise engaged in the shared purposes of exchanging inflated reported prices and secret refund

payments for preferred formulary positions for Eli Lilly's diabetes medications in order to profit off the public and Plaintiff Harris County.

384. Each of the Eli Lilly-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties and continuing coordination of activities between Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, Eli Lilly and OptumRx and Eli Lilly and Aetna Rx.

385. As to each of these Eli Lilly-PBM Enterprises, there is a common communication network by which Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, Eli Lilly and OptumRx and Eli Lilly and Aetna Rx share information and meet on a regular basis. These communications relate to the use of the reported prices of diabetes medications and the regular flow of payments from Eli Lilly to each PBM Defendant for formulary placement, including: (i) access rebates for placement of products on their formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) undisclosed administrative fees; and (iv) other fees and grants in an effort to promote products.

386. As to each of these Eli Lilly-PBM Enterprises, Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, Eli Lilly and OptumRx and Eli Lilly and Aetna Rx function as continuing but separate units.

387. At all relevant times, each of the Eli Lilly-PBM Enterprises was operated and conducted by Eli Lilly and each PBM Defendant for unlawful purposes, namely, carrying out the Insulin Pricing Scheme.

388. From these activities, each Eli Lilly-PBM Enterprise derived secret profits that are greater than either Eli Lilly or any one of the PBM Defendants could obtain absent their misrepresentations regarding their non-transparent pricing schemes.

389. To accomplish this common purpose, each Eli Lilly-PBM Enterprise periodically and systematically inflated the reported prices of Humulin N, Humulin R, Humalog, Trulicity and Basaglar and then secretly paid a significant, yet undisclosed, portion of this inflated price back to PBM Defendants in the form of rebates, administrative fees and other “soft dollars.”

390. Each Eli Lilly-PBM Enterprise did so willfully, and with knowledge that Plaintiff Harris County paid for the at issue drugs at a price directly based on Eli Lilly’s reported price.

391. Eli Lilly’s inflation of its reported prices and secret payments were a *quid pro quo* exchange with each PBM Defendant for preferred formulary placement.

392. Each Eli Lilly-PBM Enterprise concealed from the public and Harris County that these inflated reported prices and secret payments resulted in higher profits for Eli Lilly, through ensuring formulary access without requiring significant price reductions; and they resulted in higher profits for each PBM Defendant, whose earnings increase the more inflated the reported price is and the more payment it receives from Eli Lilly.

393. Each Eli Lilly-PBM Enterprise also shares a common purpose of perpetuating the use of the reported prices of diabetes medications as the basis for the price that payors’ pay for diabetes medications.

394. Eli Lilly would not be able to market large pricing spreads to PBM Defendants in exchange for favorable formulary positions without the use of the inflated reported prices as the basis for the price paid by payors, including Plaintiff Harris County, for the at issue drugs.

395. Each PBM Defendant shares this common purpose because, without payors, including Harris County, paying for diabetes medications based on the inflated reported prices, their profits from the Insulin Pricing Scheme would collapse.

396. As a result, each PBM Defendant has, with the knowing and willful participation and assistance of Eli Lilly, engaged in hidden profit-making schemes falling into four general categories: (i) garnering undisclosed rebates and other “soft dollars” from Eli Lilly that each PBM Defendant, to a large extent, keep; (ii) pocketing secret spreads including the Pharmacy Spread described above; (iii) creating large profit margins on the diabetes medications sold through each PBM Defendants’ own mail order pharmacies and (iv) keeping secret discounts Eli Lilly provides in association with each PBM Defendants’ mail order operations.

397. At all relevant times, each PBM Defendant and Eli Lilly has been aware of their respective Eli Lilly-PBM Enterprise’s conduct, has been a knowing and willing participant in and coordinator of that conduct and has reaped profits from that conduct.

398. But for each Eli Lilly-PBM Enterprise’s common purpose of engaging in the Insulin Pricing Scheme, Eli Lilly and each PBM Defendant would have had the incentive to disclose the fraudulence of the scheme.

399. By failing to disclose this fraud, Eli Lilly and each PBM Defendant has perpetuated the conduct of the Eli Lilly-PBM Enterprises.

400. Each Eli Lilly-PBM Enterprise knowingly made the following material misrepresentations to the public and Plaintiff Harris County in furtherance of the fraudulent scheme:

- a. That Eli Lilly’s published, reported prices of diabetes medications resulted from transparent and competitive market forces and were a reasonable

and fair basis on which to base the price Plaintiff Harris County paid for these drugs;

b. That the payments Eli Lilly paid back to each PBM Defendant for each at issue drug sold was for the benefit of Plaintiff Harris County;

c. That Eli Lilly and each PBM Defendant were transparent with Plaintiff Harris County, regarding these payments and that these payments did, in fact, save Harris County and the general public money;

d. That PBM Defendants' "preferred" formulary status of diabetes medications reflects the drugs' safety, efficacy and cost-effectiveness, as determined by PBM Defendants' formulary committees and were constructed for the benefit of payors, including Harris County; and

e. The extent to which the Insulin Pricing Scheme forced Harris County to incur additional expenses for diabetes medications.

401. At all times relevant to this Complaint, each Eli Lilly-PBM Enterprise knew that these representations were false.

402. At all times relevant to this Complaint, each Eli Lilly-PBM Enterprise intentionally made these representations for the purpose of inducing payors, including Harris County, into paying for diabetes medications at artificially inflated prices.

403. Plaintiff Harris County relied on the material misrepresentations made by each Eli Lilly-PBM Enterprise in paying prices for Eli Lilly's diabetes medications based upon the artificially inflated reported prices.

404. None of the PBM Defendants nor Eli Lilly alone could have accomplished the purposes of the Eli Lilly-PBM Enterprise without the other entity.

405. Each PBM Defendant needs Eli Lilly to artificially inflate its reported prices and to pay large refund payments back to the PBM Defendant.

406. For Eli Lilly to profit from the scheme, each PBM Defendant needed to convince payors, including Plaintiff Harris County, to select their formularies, on which varying diabetes medications were given favorable treatment and to pay prices based upon the artificially inflated reported price.

407. And PBM Defendants did so utilizing the misrepresentations listed above to convince Plaintiff Harris County that they secured lower prices.

408. Without these misrepresentations, each Eli Lilly-PBM Enterprise could not have achieved its common purpose as Plaintiff Harris County would not have been willing to pay based upon these artificially raised and unreasonable prices.

409. The foregoing evidences that Eli Lilly and PBM Defendants were each willing participants in the Eli Lilly-PBM Enterprises, had a common fraudulent purpose and interest in the objective of the scheme, and functioned within a structure designed to effectuate the Enterprises' purposes, *i.e.*, to increase profits for Eli Lilly and each PBM Defendant at the expense of payors, including Plaintiff Harris County.

C. Defendants' Use of the U.S. Mails and Interstate Wire Facilities

410. Each of the Eli Lilly-PBM Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: the sale, purchase and/or administration of diabetes medications; the setting and publishing of the prices of these drugs; and/or the transmission of pricing information of diabetes medications; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission of diabetes medications through mail-order pharmacies; and/or the transmission and/or receipt of invoices, statements, and payments related to the use

or administration of diabetes medications; and/or the negotiations and transmissions of contracts related to the pricing of and payment for diabetes medications.

411. Each Eli Lilly-PBM Enterprise participated in the administration of diabetes medications to millions of individuals located throughout the United States, including to Plaintiff Harris County's Beneficiaries in Texas.

412. Eli Lilly and each PBM Defendant's illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

413. The nature and pervasiveness of the Insulin Pricing Scheme, which was orchestrated out of Eli Lilly's and each PBM Defendant's corporate headquarters, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with each other.

414. Most of the precise dates of Eli Lilly's and each PBM Defendant's uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to each entity's books and records. Indeed, an essential part of the successful operation of the Insulin Pricing Scheme depended upon secrecy, as alleged above. And Eli Lilly and each PBM Defendant took deliberate steps to conceal their wrongdoing.

415. Plaintiff can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the Insulin Pricing Scheme.

416. Eli Lilly and each PBM Defendant's use of the U.S. mails and interstate wire facilities to perpetrate the Insulin Pricing Scheme involved thousands of communications including, *inter alia*:

a. Marketing materials about the reported prices for diabetes medications and the available spreads, which Eli Lilly sent to each PBM Defendant located across the country;

b. Written and oral representations of the reported prices of diabetes medications that Eli Lilly and each PBM Defendant made at least annually and, in many cases, several times during a single year, including directly to Plaintiff Harris County;

c. Thousands of written and oral communications discussing, negotiating and confirming the placement of Eli Lilly's diabetes medications on a particular PBM Defendant's formulary;

d. Written and oral representations made by Eli Lilly regarding information or incentives paid back to each PBM Defendant for each diabetes medications sold and/or to conceal these incentives or the Insulin Pricing Scheme;

e. Written communications made by Eli Lilly, including checks, relating to rebates or other financial inducements paid to each PBM Defendant to persuade them to advocate Eli Lilly's diabetes medications;

f. Written and oral communications with U.S. government agencies and payors, such as Plaintiff Harris County, that fraudulently misrepresented what the reported prices were or that they were intended to deter investigations into the true nature of the reported prices or to forestall changes to reimbursement based on something other than reported prices;

g. Written and oral communications with Plaintiff Harris County, regarding and/or negotiating the price of diabetes medications;

h. Written and oral communications to Plaintiff Harris County, including marketing and solicitation material sent by each PBM Defendant at least in 2003, 2008 and 2016, as well as annual written reports, regarding the existence, amount, or purpose of payments made by Eli Lilly to each PBM Defendant for the diabetes medications described herein and the purpose of PBM Defendants' formularies;

i. Transmission of reported prices to third parties, including Plaintiff Harris County;

j. Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities—the wrongful proceeds of the Insulin Pricing Scheme; and

k. In addition to the above-referenced RICO predicate acts, Eli Lilly's and each PBM Defendant's corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions, in furtherance of the Insulin Pricing Scheme, including within Texas.

D. Conduct of Eli Lilly-PBM Enterprises' Affairs

417. Eli Lilly and each PBM Defendant has participated in and exerted control over the Eli Lilly-PBM Enterprises with which they were associated and, in violation of Section 1962(c) of RICO, Eli Lilly and each PBM Defendant has conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation was carried out in the following ways:

a. Eli Lilly directly controls the secret payments it provides to PBM Defendants for its diabetes medications, which determines the amount of each PBM Defendants' compensation from Eli Lilly;

b. PBM Defendants directly control their respective drug formularies, which determines the utilization of Eli Lilly's diabetes medications;

c. Eli Lilly directly controls the prices that it publicly reports;

d. Eli Lilly directly controls the creation and distribution of marketing, sales and other materials used to inform each PBM Defendant of the profit potential from its diabetes medications;

e. Each PBM Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform payors of the benefits and cost-saving potential of contracting with PBMs;

f. Each PBM Defendant and Eli Lilly has relied upon its employees and agents to promote the Insulin Pricing Scheme through the U.S. mails, through interstate wire facilities and through direct contacts with providers and payors; and

g. Eli Lilly has controlled and participated in the affairs of each Eli Lilly-PBM Enterprises by providing payments and/or other inducements to place Eli Lilly's diabetes medications on each PBM Defendants' formularies or advocate the use of certain diabetes medications. These inducements include Eli Lilly's payment to each PBM Defendant of: (i) access rebates for placement of products on the PBMs' formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) undisclosed administrative fees; and (iv) other fees and grants.

h. Each PBM Defendant has controlled and participated in the affairs of the Eli Lilly-PBM Enterprise with which it is associated by incentivizing and agreeing with Eli Lilly to exchange formulary placement for inflated reported prices and payments as described above. Furthermore, PBM Defendants hide the actual amount of secret refund payments received from Eli Lilly by relabeling them discounts, credits, concession fees, administrative fees, etc. and then not disclosing the amount paid under these labels.

i. Each PBM Defendant did distribute through the U.S. mail and interstate wire facilities, promotional and other materials which claimed that the money paid from Eli Lilly to each PBM Defendant saved payors, like Plaintiff Harris County, money on their prescription needs.

j. Eli Lilly represented to the general public and Harris County—by publishing and promoting reported prices without stating that these reported prices differed substantially from the prices realized by Eli Lilly and each PBM Defendant—that the reported prices of diabetes medications reflected or approximated the net price realized by Defendants and resulted from transparent and competitive market forces.

k. Each of the Eli Lilly-PBM Enterprises identified above had hierarchical decision-making structure headed by Eli Lilly and each PBM Defendant.

l. In violation of Section 1962(c) of RICO, Eli Lilly and each PBM Defendant has conducted the affairs of each of the Eli Lilly-PBM Enterprises with which they associated in order to carry out the Insulin Pricing Scheme.

E. Defendants' Pattern of Racketeering Activity

418. Eli Lilly and each PBM Defendant has conducted and participated in the affairs of their respective Eli Lilly-PBM Enterprises through a pattern of racketeering activity, including acts that are unlawful under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud.

419. Eli Lilly's and each PBM Defendant's pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of the Insulin Pricing Scheme described above. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which Eli Lilly and each PBM Defendant intended to defraud Plaintiff Harris County.

420. By intentionally and artificially inflating the reported prices, by misrepresenting the purpose behind both the payments made from Eli Lilly to each PBM Defendant and each PBM Defendant's formulary decisions and by subsequently failing to disclose such practices to the public and Harris County, Eli Lilly and each PBM Defendant engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

421. Eli Lilly's and each PBM Defendant's racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive payors, including Harris County.

422. Each separate use of the U.S. mails and/or interstate wire facilities employed by Eli Lilly and each PBM Defendant was related, had similar intended

purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Harris County.

423. Eli Lilly and each PBM Defendant engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the respective Eli Lilly-PBM Enterprises with which each of them is and was associated in fact.

F. Defendants' Motive

424. Eli Lilly's and each PBM Defendant's motives in creating and operating the Insulin Pricing Scheme and conducting the affairs of the Eli Lilly-PBM Enterprises described herein was to fraudulently obtain sales of and profits from diabetes medications.

425. The Insulin Pricing Scheme was designed to, and did, encourage others, including payors, such as Harris County, to advocate the use of Eli Lilly's products and to pay for those diabetes medications based on a fraudulently inflated price. Eli Lilly used the Insulin Pricing Scheme to obtain formulary placement to sell more of its drugs without having to cut into its profit margin. Each PBM Defendant used the Insulin Pricing Scheme to inflate the price payors such as Plaintiff Harris County paid for diabetes medications in order to profit off the Secret Payment Game, the Pharmacy Spread and their mail order pharmacies, as discussed above.

G. Eli Lilly-PBM Enterprises' Insulin Pricing Scheme Damaged Harris County

426. Each Eli Lilly-PBM Enterprise's violations of federal law and pattern of racketeering activity has directly and proximately caused Plaintiff Harris County to be injured in its business or property.

427. The price Harris County pays for Humulin N, Humulin R, Humalog, Trulicity and Basaglar is directly tied to Eli Lilly's reported prices.

428. No other intermediary in the supply chain has control over or is responsible for the reported prices on which Harris County's payments are based other than the Eli Lilly-PBM Defendant Enterprises.

429. PBM Defendants set the price by which Harris County paid for the at issue diabetes medications. PBM Defendants also receive payments made by Harris County for the at issue diabetes medications.

430. During the relevant time period, each PBM Defendant provided PBM services to Plaintiff Harris County.

431. The entire basis behind each Eli Lilly-PBM Enterprise's fraudulent scheme was to convince payors, such as Harris County, to pay inflated prices for diabetes medications in order to make enormous profits.

432. Each Eli Lilly-PBM Enterprise controlled and participated in the Insulin Pricing Scheme that was directly responsible for the artificially inflated reported prices upon which the price Harris County paid was based.

433. Thus, Harris County was damaged as a result of the Insulin Pricing Scheme. But for the misrepresentations and inflated prices created by the Insulin Pricing Scheme that each Eli Lilly-PBM Enterprise employed, Harris County would have paid less for diabetes medications.

434. As explained above, Harris County's damages are the difference between the price that Harris County paid for the at issue drugs and what it would have paid absent the Insulin Pricing Scheme.

435. Harris County was directly harmed by the Insulin Pricing Scheme and is entitled to seek a remedy for the economic harms to Harris County from Defendants' fraudulent scheme.

436. Harris County's damages are separate and distinct from any other victim that was harmed by the Eli Lilly-PBM Defendant Enterprises' Insulin Pricing Scheme.

437. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Harris County for three times the damages that Harris County has sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

438. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(a) of RICO, Plaintiff Harris County seeks injunctive relief against Eli Lilly and PBM Defendants for their fraudulent reporting of their prices and their continuing acts to affirmatively misrepresent and/or conceal and suppress material facts concerning their artificially inflated prices for diabetes medications, plus the costs of bringing this suit, including reasonable attorneys' fees. Absent an injunction, the effects of this fraudulent, unfair and unconscionable conduct will continue. Plaintiff Harris County continues to purchase Eli Lilly's diabetes medications. And Harris County will continue to pay based on the Defendants' fraudulent reported prices. This continuing fraudulent, unfair and unconscionable conduct is a serious matter that calls for injunctive relief as a remedy. Plaintiff Harris County seeks injunctive relief, including an injunction against Eli Lilly and PBM Defendants, to prevent them from affirmatively misrepresenting and/or concealing and suppressing material facts concerning their artificially inflated prices for diabetes medications.

SECOND CAUSE OF ACTION

Violations of RICO, 18 U.S.C. § 1962(c) (Against Novo Nordisk and All PBM Defendants)

439. Plaintiff Harris County re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

440. This cause of action is brought by Plaintiff Harris County against Defendants Novo Nordisk, Express Scripts, CVS Caremark, OptumRx and Aetna Rx for violations of 18 U.S.C. § 1962(c).

441. Defendants Novo Nordisk, Express Scripts, CVS Caremark, OptumRx and Aetna Rx are (a) culpable “persons” who (b) willfully and knowingly (c) committed and conspired to the commission of mail and wire fraud (d) through a “pattern” (e) involving an “association in fact,” (f) the results of which had an effect on interstate commerce.

A. Defendants are Culpable “Persons” Under RICO.

442. Defendants Novo Nordisk, Express Scripts, CVS Caremark, OptumRx and Aetna Rx, separately, are “persons” as that term is defined in 18 U.S.C. § 1961(3) because each is capable of holding a legal or beneficial interest in property.

443. Each one of Defendants Novo Nordisk, Express Scripts, CVS Caremark, OptumRx and Aetna Rx are separate entities and “persons” that are distinct from the RICO enterprises alleged below.

B. Novo Nordisk-PBM RICO Enterprises

444. For the purposes of this claim, the RICO enterprises are four separate associations-in-fact consisting of one of each of the PBM Defendants that administers purchases of Novo Nordisk’s Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza and Ozempic, including those entities’ directors, employees, and agents, and Novo

Nordisk, including its directors, employees and agents: (1) the Novo Nordisk-CVS Caremark association-in-fact enterprise; (2) the Novo Nordisk-Express Scripts association-in-fact enterprise; (3) the Novo Nordisk-OptumRx association-in-fact enterprise; and (4) the Novo Nordisk-Aetna Rx association-in-fact enterprise (collectively, “Novo Nordisk-PBM Enterprises”).

445. Each Novo Nordisk-PBM Enterprise is a separate ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common and/or shared purposes of manufacturing, selling, facilitating the purchase of and profiting from the sale of Novo Nordisk’s Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza and Ozempic to the public and Plaintiff Harris County.

446. With respect to the Insulin Pricing Scheme, each Novo Nordisk-PBM Enterprise engaged in the shared purposes of exchanging inflated reported prices and secret payments for preferred formulary positions for Novo Nordisk’s diabetes medications in order to profit off Plaintiff Harris County and the public.

447. Each of the Novo Nordisk-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties and continuing coordination of activities between Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, Novo Nordisk and OptumRx and Novo Nordisk and Aetna Rx.

448. As to each of these Novo Nordisk-PBM Enterprises, there is a common communication network by which Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, Novo Nordisk and OptumRx and Novo Nordisk and Aetna Rx share information and meet on a regular basis. These communications relate to the use of the reported prices of diabetes medications and the regular flow of payments from Novo

Nordisk to each PBM Defendant for formulary placement, including: (i) access rebates for placement of products on their formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) undisclosed administrative fees; and (iv) other fees and grants in an effort to promote products.

449. As to each of these Novo Nordisk-PBM Enterprises, Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, Novo Nordisk and OptumRx and Novo Nordisk and Aetna Rx function as continuing but separate units.

450. At all relevant times, each of the Novo Nordisk-PBM Enterprises was operated and conducted by Novo Nordisk and each PBM Defendant for unlawful purposes, namely, carrying out the Insulin Pricing Scheme.

451. From these activities, each Novo Nordisk-PBM Enterprise derived secret profits that are greater than either Novo Nordisk or any one of the PBM Defendants could obtain absent their misrepresentations regarding each enterprises' non-transparent pricing schemes.

452. To accomplish this common purpose, each Novo Nordisk-PBM Enterprise periodically and systematically inflated the reported prices of Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza and Ozempic and then secretly paid a significant, yet undisclosed, portion of this inflated price back to PBM Defendants in the form of rebates, administrative fees and other "soft dollars."

453. Each Novo Nordisk-PBM Enterprise did so willfully, and with knowledge that Plaintiff Harris County and third-party payers make payments directly based on Novo Nordisk's reported price.

454. Novo Nordisk's inflation of its reported prices and payment of secret refund payments were a *quid pro quo* exchange with each PBM Defendant for preferred formulary placement.

455. Each Novo Nordisk-PBM Enterprise concealed from the public and Plaintiff Harris County that these inflated reported prices and secret payments resulted in higher profits for Novo Nordisk, through ensuring formulary access without requiring significant price reductions; and they resulted in higher profits for each PBM Defendant, whose earnings increase the more inflated the reported price is and the more refund payments it receives.

456. Each Novo Nordisk-PBM Enterprise also shares a common purpose of perpetuating the use of the reported prices of diabetes medications as the basis for the price that Plaintiff Harris County pays for diabetes medications.

457. Novo Nordisk would not be able to market large pricing spreads to PBM Defendants in exchange for favorable formulary positions without the use of the inflated reported prices as the basis for the price paid by Plaintiff Harris County for the at issue drugs.

458. Each PBM Defendant shares this common purpose because, without payors, including Harris County, paying for diabetes medications based on the inflated reported prices, their profits from the Insulin Pricing Scheme would collapse.

459. As a result, each PBM Defendant has, with the knowing and willful participation and assistance of Novo Nordisk, engaged in hidden profit-making schemes falling into four general categories: (i) garnering undisclosed payments and other "soft dollars" from Novo Nordisk that each PBM Defendant, to a large extent, keep; (ii) pocketing secret spreads including the Pharmacy Spread described above; (iii) creating

large profit margins on the diabetes medications sold through each PBM Defendants' own mail order pharmacies and (iv) keeping secret discounts Novo Nordisk provides in association with each PBM Defendants' mail order operations.

460. At all relevant times, each PBM Defendant and Novo Nordisk has been aware of their respective Novo Nordisk-PBM Enterprise's conduct, has been a knowing and willing participant in and coordinator of that conduct and has reaped profits from that conduct.

461. But for each Novo Nordisk-PBM Enterprise's common purpose of enlarging the hidden spreads between net and reported price, Novo Nordisk and each PBM Defendant would have had the incentive to disclose the fraudulence of the Insulin Pricing Scheme.

462. By failing to disclose this fraud, Novo Nordisk and each PBM Defendant has perpetuated the conduct of the Novo Nordisk-PBM Enterprises.

463. Each Novo Nordisk-PBM Enterprise knowingly made the following material misrepresentations to the public and Plaintiff Harris County in furtherance of the fraudulent scheme:

a. That Novo Nordisk's published, reported prices of diabetes medications resulted from transparent and competitive market forces and were a reasonable and fair basis on which to base the price Plaintiff Harris County paid for these drugs;

b. That the payments Novo Nordisk paid back to each PBM Defendant for each at issue drug sold was for the benefit of Plaintiff Harris County;

c. That Novo Nordisk and each PBM Defendant were transparent with Plaintiff Harris County, regarding these payments and that these payments did, in fact, save Harris County and the general public money;

d. That PBM Defendants' "preferred" formulary status of diabetes medications reflects the drugs' safety, efficacy and cost-effectiveness, as determined by PBM Defendants' formulary committees and were constructed for the benefit of payors, including Harris County; and

e. The extent to which the Insulin Pricing Scheme forced Harris County to incur additional expenses for diabetes medications.

464. At all times relevant to this Complaint, each Novo Nordisk-PBM Enterprise knew that these representations were false.

465. At all times relevant to this Complaint, each Novo Nordisk-PBM Enterprise intentionally made these representations for the purpose of inducing payors, including Harris County, into paying for diabetes medications at artificially inflated prices.

466. Plaintiff Harris County relied on the material misrepresentations made by each Novo Nordisk-PBM Enterprise in paying prices for Novo Nordisk's diabetes medications based upon the artificially inflated reported prices.

467. None of the PBM Defendants nor Novo Nordisk alone could have accomplished the purposes of the Novo Nordisk-PBM Enterprise without the other entity.

468. Each PBM Defendant needs Novo Nordisk to artificially inflate its reported prices and to pay large secret payments back to the PBM Defendant.

469. For Novo Nordisk to profit from the scheme, each PBM Defendant needed to convince payors, such as Plaintiff Harris County, to select their formularies, on which

varying diabetes medications were given favorable treatment and to pay prices based upon the artificially inflated reported price.

470. And PBM Defendants did so utilizing the misrepresentations listed above to convince Plaintiff Harris County that they secured lower prices.

471. Without these misrepresentations, each Novo Nordisk-PBM Enterprise could not have achieved its common purpose as Plaintiff Harris County would not have been willing to pay based upon these artificially raised and unreasonable prices.

472. The foregoing evidences that Novo Nordisk and PBM Defendants were each willing participants in the Novo Nordisk-PBM Enterprises, had a common fraudulent purpose and interest in the objective of the scheme, and functioned within a structure designed to effectuate the Enterprises' purposes, *i.e.*, to increase profits for Novo Nordisk and each PBM Defendant at the expense of Plaintiff Harris County.

C. Defendants' Use of the U.S. Mails and Interstate Wire Facilities

473. Each of the Novo Nordisk-PBM Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: the sale, purchase and/or administration of diabetes medications; the setting and publishing of the prices of these drugs; and/or the transmission of pricing information of diabetes medications; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission of diabetes medications through mail-order pharmacies; and/or the transmission and/or receipt of invoices, statements and payments related to the use or administration of diabetes medications; and/or the negotiations and transmissions of contracts related to the pricing of and payment for diabetes medications.

474. Each Novo Nordisk-PBM Enterprise participated in the administration of diabetes medications to millions of individuals located throughout the United States, including to Plaintiff Harris County's Beneficiaries in Texas.

475. Novo Nordisk and each PBM Defendant's illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

476. The nature and pervasiveness of the Insulin Pricing Scheme, which was orchestrated out of Novo Nordisk's and each PBM Defendant's corporate headquarters, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with each other.

477. Most of the precise dates of Novo Nordisk's and each PBM Defendant's uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to each entity's books and records. Indeed, an essential part of the successful operation of the Insulin Pricing Scheme depended upon secrecy, as alleged above. And Novo Nordisk and each PBM Defendant took deliberate steps to conceal their wrongdoing.

478. Plaintiff can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the Insulin Pricing Scheme.

479. Novo Nordisk and each PBM Defendant's use of the U.S. mails and interstate wire facilities to perpetrate the Insulin Pricing Scheme involved thousands of communications including, *inter alia*:

a. Marketing materials about the reported prices for diabetes medications and the available spreads, which Novo Nordisk sent to each PBM Defendant located across the country;

b. Written and oral representations of the reported prices of diabetes medications that Novo Nordisk and each PBM Defendant made at least annually and, in many cases, several times during a single year, including directly to Plaintiff Harris County;

c. Thousands of written and oral communications discussing, negotiating and confirming the placement of Novo Nordisk's diabetes medications on a particular PBM Defendant's formulary;

d. Written and oral representations made by Novo Nordisk regarding information or incentives paid back to each PBM Defendant for each diabetes medications sold and/or to conceal these incentives or the Insulin Pricing Scheme;

e. Written communications made by Novo Nordisk, including checks, relating to payments or other financial inducements paid to each of PBM Defendants to persuade them to advocate Novo Nordisk's diabetes medications;

f. Written and oral communications with U.S. government agencies and payors, such as Plaintiff Harris County, that fraudulently misrepresented what the reported prices were, or that they were intended to deter investigations into the true nature of the reported prices or to forestall changes to reimbursement based on something other than reported prices;

g. Written and oral communications with payors, including Plaintiff Harris County, regarding and/or negotiating the price of diabetes medications;

h. Written and oral communications to Plaintiff Harris County, including marketing and solicitation material sent by each PBM Defendant at least in 2003, 2008 and 2016, as well as annual written reports, regarding the existence, amount, or purpose of payments made by Novo Nordisk to each PBM Defendant for the diabetes medications described herein and the purpose of PBM Defendants' formularies;

i. Transmission of reported prices to third parties, including Plaintiff Harris County;

j. Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities—the wrongful proceeds of the Insulin Pricing Scheme; and

k. In addition to the above-referenced RICO predicate acts, Novo Nordisk's and each PBM Defendant's corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions, in furtherance of the Insulin Pricing Scheme, including within Texas.

D. Conduct of Novo Nordisk-PBM Enterprises' Affairs

480. Novo Nordisk and each PBM Defendant has participated in and exerted control over the Novo Nordisk-PBM Enterprises with which they were associated and, in violation of Section 1962(c) of RICO, Novo Nordisk and each PBM Defendant has conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation was carried out in the following ways:

a. Novo Nordisk directly controls the secret payments it provides to PBM Defendants for its diabetes medications, which determines the amount of each PBM Defendant's compensation from Novo Nordisk;

b. PBM Defendants directly control their respective drug formularies, which determines the utilization of Novo Nordisk's diabetes medications;

c. Novo Nordisk directly controls the prices that it publicly reports;

d. Novo Nordisk directly controls the creation and distribution of marketing, sales and other materials used to inform each PBM Defendant of the profit potential from its diabetes medications;

e. Each PBM Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform payors of the benefits and cost-saving potential of contracting with PBMs;

f. Each PBM Defendant and Novo Nordisk has relied upon its employees and agents to promote the Insulin Pricing Scheme through the U.S. mails, through interstate wire facilities, and through direct contacts with providers and payors; and

g. Novo Nordisk has controlled and participated in the affairs of each Novo Nordisk-PBM Enterprises by providing secret payments and/or other inducements to place Novo Nordisk's diabetes medications on each PBM Defendant's formularies or advocate the use of certain diabetes medications. These inducements include Novo Nordisk's payment to each PBM Defendant of: (i) access rebates for placement of products on the PBMs' formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) undisclosed administrative fees; and (iv) other fees and grants.

h. Each PBM Defendant has controlled and participated in the affairs of the Novo Nordisk-PBM Enterprise with which it is associated by incentivizing and agreeing with Novo Nordisk to exchange formulary placement for inflated reported prices and payments as described above. Furthermore, PBM Defendants hide the actual amount of secret payments received from Novo Nordisk by relabeling them discounts, credits, concession fees, administrative fees, etc. and then not disclosing the amount paid under these labels.

i. Each PBM Defendant did distribute through the U.S. mail and interstate wire facilities, promotional and other materials which claimed that the money paid from Novo Nordisk to each PBM Defendant saved payors, like Plaintiff Harris County, money on their prescription needs.

j. Novo Nordisk represented to the general public and Harris County—by publishing and promoting reported prices without stating that these reported prices differed substantially from the prices realized by Novo Nordisk and each PBM Defendant—that the reported prices of diabetes medications reflected or approximated the net prices and resulted from transparent and competitive market forces.

k. Each of the Novo Nordisk-PBM Enterprises identified above had hierarchical decision-making structure headed by Novo Nordisk and each PBM Defendant.

l. In violation of Section 1962(c) of RICO, Novo Nordisk and each PBM Defendant has conducted the affairs of each of the Novo Nordisk-PBM Enterprises with which they associated in order to carry out the Insulin Pricing Scheme.

E. Defendants' Pattern of Racketeering Activity

481. Novo Nordisk and each PBM Defendant has conducted and participated in the affairs of their respective Novo Nordisk-PBM Enterprises through a pattern of racketeering activity, including acts that are unlawful under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud.

482. Novo Nordisk's and each PBM Defendant's pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of the Insulin Pricing Scheme described above. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which Novo Nordisk and each PBM Defendant intended to defraud Plaintiff Harris County.

483. By intentionally and artificially inflating the reported prices, by misrepresenting the purpose behind both the payments made from Novo Nordisk to each PBM Defendant and each PBM Defendant's formulary decisions and by subsequently failing to disclose such practices to the public and Harris County, Novo Nordisk and each PBM Defendant engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

484. Novo Nordisk's and each PBM Defendant's racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive Plaintiff Harris County.

485. Each separate use of the U.S. mails and/or interstate wire facilities employed by Novo Nordisk and each PBM Defendant was related, had similar intended

purposes, involved similar participants and methods of execution and had the same results affecting the same victims, including Plaintiff Harris County.

486. Novo Nordisk and each PBM Defendant engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the respective Novo Nordisk-PBM Enterprises with which each of them is and was associated in fact.

F. Defendants' Motive

487. Novo Nordisk's and each PBM Defendant's motives in creating and operating the Insulin Pricing Scheme and conducting the affairs of the Novo Nordisk-PBM Enterprises described herein was to fraudulently obtain sales of and profits from diabetes medications.

488. The Insulin Pricing Scheme was designed to, and did, encourage others, including payors, such as Harris County, to advocate the use of Novo Nordisk's products and to pay for those diabetes medications based on fraudulently inflated prices. Novo Nordisk used the Insulin Pricing Scheme to obtain formulary placement to sell more of its drugs without having to cut into its profit margin. Each PBM Defendant used the Insulin Pricing Scheme to inflate the price payors such as Plaintiff Harris County paid for diabetes medications in order to profit off the Secret Payment Game, the Pharmacy Spread and their mail order pharmacies, as discussed above.

G. Novo Nordisk-PBM Enterprises' Insulin Pricing Scheme Damaged Harris County

489. Each Novo Nordisk-PBM Enterprise's violations of federal law and pattern of racketeering activity has directly and proximately caused Plaintiff Harris County to be injured in its business or property.

490. The price Harris County pays for Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza and Ozempic is directly tied to Novo Nordisk's reported prices.

491. No other intermediary in the supply chain has control over or is responsible for the reported prices on which Harris County's payments are based other than the Novo Nordisk-PBM Defendant Enterprises.

492. PBM Defendants set the price by which Harris County paid for the at issue diabetes medications. PBM Defendants also receive payments made by Harris County for the at issue diabetes medications.

493. During the relevant time period, each PBM Defendant provided PBM services to Plaintiff Harris County.

494. The entire basis behind each Novo Nordisk-PBM Enterprise's fraudulent scheme was to convince payors, such as Harris County, to pay inflated prices for diabetes medications in order to make enormous profits.

495. Each Novo Nordisk-PBM Enterprise controlled and participated in the Insulin Pricing Scheme that was directly responsible for the artificially inflated reported prices upon which the price Harris County paid was based.

496. Thus, Harris County was damaged as a result of the Insulin Pricing Scheme. But for the misrepresentations and inflated prices created by the Insulin Pricing Scheme that each Novo Nordisk-PBM Enterprise employed, Harris County would have paid less for diabetes medications.

497. As explained above, Harris County's damages are the difference between the price that Harris County paid for the at issue drugs and what it would have paid absent the Insulin Pricing Scheme.

498. Harris County was directly harmed by the Insulin Pricing Scheme and is entitled to seek a remedy for the economic harms to Harris County from Defendants' fraudulent scheme.

499. Harris County's damages are separate and distinct from any other victim that was harmed by the Novo Nordisk-PBM Defendant Enterprises' Insulin Pricing Scheme.

500. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Harris County for three times the damages that Harris County has sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

501. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964 of RICO, Plaintiff Harris County seeks injunctive relief against Novo Nordisk and PBM Defendants for their fraudulent reporting of their prices and their continuing acts to affirmatively misrepresent and/or conceal and suppress material facts concerning their artificially inflated prices for diabetes medications, plus the costs of bringing this suit, including reasonable attorneys' fees. Absent an injunction, the effects of this fraudulent, unfair and unconscionable conduct will continue. Plaintiff Harris County continues to purchase Novo Nordisk's diabetes medications. And Harris County will continue to pay based on the Defendants' fraudulent reported prices. This continuing fraudulent, unfair and unconscionable conduct is a serious matter that calls for injunctive relief as a remedy. Plaintiff Harris County seeks injunctive relief, including an injunction against Novo Nordisk and PBM Defendants, to prevent them from affirmatively misrepresenting and/or concealing and suppressing material facts concerning their artificially inflated prices for diabetes medications.

THIRD CAUSE OF ACTION

Violations of RICO, 18 U.S.C. § 1962(c) (Against Sanofi and All PBM Defendants)

502. Plaintiff Harris County re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

503. This cause of action is brought by Plaintiff Harris County against Defendants Sanofi, Express Scripts, CVS Caremark, OptumRx and Aetna Rx for violations of 18 U.S.C. § 1962(c).

504. Defendants Sanofi, Express Scripts, CVS Caremark, OptumRx and Aetna Rx are (a) culpable “persons” who (b) willfully and knowingly (c) committed and conspired to the commission of mail and wire fraud (d) through a “pattern” (e) involving an “association in fact,” (f) the results of which had an effect on interstate commerce.

A. Defendants Are Culpable “Persons” Under RICO.

505. Defendants Sanofi, Express Scripts, CVS Caremark, OptumRx and Aetna Rx, separately, are “persons” as that term is defined in 18 U.S.C. § 1961(3) because each is capable of holding a legal or beneficial interest in property.

506. Each one of Defendants Sanofi, Express Scripts, CVS Caremark, OptumRx and Aetna Rx are separate entities and “persons” that are distinct from the RICO enterprises alleged below.

B. Sanofi-PBM RICO Enterprises

507. For the purposes of this claim, the RICO enterprises are four separate associations-in-fact consisting of one of each of the PBM Defendants that administers purchases of Sanofi’s Lantus, Toujeo, Soliqua and Apidra, including those entities’ directors, employees, and agents, and Sanofi, including its directors, employees and

agents: (1) the Sanofi-CVS Caremark association-in-fact enterprise; (2) the Sanofi-Express Scripts association-in-fact enterprise; (3) the Sanofi-OptumRx association-in-fact enterprise; and (4) the Sanofi-Aetna Rx association-in-fact enterprise (collectively, “Sanofi-PBM Enterprises”).

508. Each Sanofi-PBM Enterprise is a separate ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common and/or shared purposes of manufacturing, selling, facilitating the purchase of, and profiting from the sale of Sanofi’s Lantus, Toujeo, Soliqua and Apidra to the public and payors, including Plaintiff Harris County.

509. With respect to the Insulin Pricing Scheme, each Sanofi-PBM Enterprise engaged in the shared purposes of exchanging inflated reported prices and secret payments for preferred formulary positions for Sanofi’s diabetes medications in order to profit off payors, like Harris County, and the public.

510. Each of the Sanofi-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties and continuing coordination of activities between Sanofi and CVS Caremark, Sanofi and Express Scripts, Sanofi and OptumRx and Sanofi and Aetna Rx.

511. As to each of these Sanofi-PBM Enterprises, there is a common communication network by which Sanofi and CVS Caremark, Sanofi and Express Scripts, Sanofi and OptumRx and Sanofi and Aetna Rx share information and meet on a regular basis. These communications relate to the use of the reported prices of diabetes medications and the regular flow of payments from Sanofi to each PBM Defendant for formulary placement, including: (i) access rebates for placement of products on their formulary; (ii) market share rebates for garnering higher market share than established

targets; (iii) undisclosed administrative fees; and (iv) other fees and grants in an effort to promote products.

512. As to each of these Sanofi-PBM Enterprises, Sanofi and CVS Caremark, Sanofi and Express Scripts, Sanofi and OptumRx and Sanofi and Aetna Rx function as continuing but separate units.

513. At all relevant times, each of the Sanofi-PBM Enterprises was operated and conducted by Sanofi and each PBM Defendant for unlawful purposes, namely, carrying out the Insulin Pricing Scheme.

514. From these activities, each Sanofi-PBM Enterprise derived secret profits that are greater than either Sanofi or any one of the PBM Defendants could obtain absent their misrepresentations regarding their “rebates” and non-transparent pricing schemes.

515. To accomplish this common purpose, each Sanofi-PBM Enterprise periodically and systematically inflated the reported prices of Lantus, Toujeo, Soliqua and Apidra and then secretly paid a significant, yet undisclosed, portion of this inflated price back to PBM Defendants in the form of rebates, administrative fees and other “soft dollars.”

516. Each Sanofi-PBM Enterprise did so willfully, and with knowledge that Plaintiff Harris County and third-party payers make payments directly based on Sanofi’s reported price.

517. Sanofi’s inflation of its reported prices and payment of secret refund payments were a *quid pro quo* exchange with each PBM Defendant for preferred formulary placement.

518. Each Sanofi-PBM Enterprise concealed from the public and Harris County that these inflated reported prices and secret payments resulted in higher profits for

Sanofi, through ensuring formulary access without requiring significant price reductions; and they resulted in higher profits for each PBM Defendant, whose earnings increase the more inflated the reported price is and the more refund payments it receives.

519. Each Sanofi-PBM Enterprise also shares a common purpose of perpetuating the use of the reported prices of diabetes medications as the basis for the price that Plaintiff Harris County pays for diabetes medications.

520. Sanofi would not be able to market large pricing spreads to PBM Defendants in exchange for favorable formulary positions without the use of the inflated reported prices as the basis for the price paid by Harris County for the at issue drugs.

521. Each PBM Defendant shares this common purpose because, without payors, including Harris County, paying for diabetes medications based on the inflated reported prices, their profits from the Insulin Pricing Scheme would collapse.

522. As a result, each PBM Defendant has, with the knowing and willful participation and assistance of Sanofi, engaged in hidden profit-making schemes falling into four general categories: (i) garnering undisclosed refunds and other “soft dollars” from Sanofi that each PBM Defendant, to a large extent, keep; (ii) pocketing secret spreads including the Pharmacy Spread described above; (iii) creating large profit margins on the diabetes medications sold through each PBM Defendants’ own mail order pharmacies and (iv) keeping secret discounts Sanofi provides in association with each PBM Defendants’ mail order operations.

523. At all relevant times, each PBM Defendant and Sanofi has been aware of their respective Sanofi-PBM Enterprise’s conduct, has been a knowing and willing participant in and coordinator of that conduct and has reaped profits from that conduct.

524. But for each Sanofi-PBM Enterprise's common purpose of enlarging the hidden spreads between net and reported price, Sanofi and each PBM Defendant would have had the incentive to disclose the fraudulence of the Insulin Pricing Scheme.

525. By failing to disclose this fraud, Sanofi and each PBM Defendant has perpetuated the conduct of the Sanofi-PBM Enterprises.

526. Each Sanofi-PBM Enterprise knowingly made the following material misrepresentations to the public and Plaintiff Harris County in furtherance of the fraudulent scheme:

a. That Sanofi's published, reported prices of diabetes medications resulted from transparent and competitive market forces and were a reasonable and fair basis on which to base the price Plaintiff Harris County paid for these drugs;

b. That the payments Sanofi paid back to each PBM Defendant for each at issue drug sold was for the benefit of Plaintiff Harris County;

c. That Sanofi and each PBM Defendant were transparent with Plaintiff Harris County, regarding these payments and that these payments did, in fact, save Harris County and the general public money;

d. That PBM Defendants' "preferred" formulary status of diabetes medications reflects the drugs' safety, efficacy and cost-effectiveness, as determined by PBM Defendants' formulary committees and were constructed for the benefit of payors, including Harris County; and

e. The extent to which the Insulin Pricing Scheme forced Harris County to incur additional expenses for diabetes medications.

527. At all times relevant to this Complaint, each Sanofi-PBM Enterprise knew that these representations were false.

528. At all times relevant to this Complaint, each Sanofi-PBM Enterprise intentionally made these representations for the purpose of inducing payors, including Harris County, into paying for diabetes medications at artificially inflated prices.

529. Plaintiff Harris County relied on the material misrepresentations made by each Sanofi-PBM Enterprise in paying prices for Sanofi's diabetes medications based upon the artificially inflated reported prices.

530. None of the PBM Defendants nor Sanofi alone could have accomplished the purposes of the Sanofi-PBM Enterprise without the other entity.

531. Each PBM Defendant needs Sanofi to artificially inflate its reported prices and to pay large refund payments back to the PBM Defendant.

532. For Sanofi to profit from the scheme, each PBM Defendant needed to convince payors, including Plaintiff Harris County, to select their formularies, on which varying diabetes medications were given favorable treatment and to pay prices based upon the artificially inflated reported price.

533. And PBM Defendants did so utilizing the misrepresentations listed above to convince Plaintiff Harris County that they secured lower prices.

534. Without these misrepresentations, each Sanofi-PBM Enterprise could not have achieved its common purpose as Plaintiff Harris County would not have been willing to pay based upon these artificially raised and unreasonable prices.

535. The foregoing evidences that Sanofi and PBM Defendants were each willing participants in the Sanofi-PBM Enterprises, had a common fraudulent purpose and interest in the objective of the scheme and functioned within a structure designed to

effectuate the Enterprises' purposes, *i.e.*, to increase profits for Sanofi and each PBM Defendant at the expense of Plaintiff Harris County.

C. Defendants' Use of the U.S. Mails and Interstate Wire Facilities

536. Each of the Sanofi-PBM Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: the sale, purchase and/or administration of diabetes medications; the setting and publishing of the prices of these drugs; and/or the transmission of pricing information of diabetes medications; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission of diabetes medications through mail-order pharmacies; and/or the transmission and/or receipt of invoices, statements, and payments related to the use or administration of diabetes medications; and/or the negotiations and transmissions of contracts related to the pricing of and payment for diabetes medications.

537. Each Sanofi-PBM Enterprise participated in the administration of diabetes medications to millions of individuals located throughout the United States, including to Plaintiff Harris County's Beneficiaries in Texas.

538. Sanofi and each PBM Defendant's illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

539. The nature and pervasiveness of the Insulin Pricing Scheme, which was orchestrated out of Sanofi's and each PBM Defendant's corporate headquarters, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with each other.

540. Most of the precise dates of Sanofi's and each PBM Defendant's uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to each entity's books and records. Indeed, an essential part of the successful operation of the Insulin Pricing Scheme depended upon secrecy, as alleged above. And Sanofi and each PBM Defendant took deliberate steps to conceal their wrongdoing.

541. Plaintiff can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the Insulin Pricing Scheme.

542. Sanofi and each PBM Defendant's use of the U.S. mails and interstate wire facilities to perpetrate the Insulin Pricing Scheme involved thousands of communications including, *inter alia*:

- a. Marketing materials about the reported prices for diabetes medications and the available spreads, which Sanofi sent to each PBM Defendant located across the country;

- b. Written and oral representations of the reported prices of diabetes medications that Sanofi and each PBM Defendant made at least annually and, in many cases, several times during a single year, including directly to Plaintiff Harris County;

- c. Thousands of written and oral communications discussing, negotiating, and confirming the placement of Sanofi's diabetes medications on a particular PBM Defendant's formulary;

d. Written and oral representations made by Sanofi regarding information or incentives paid back to each PBM Defendant for each diabetes medications sold and/or to conceal these incentives or the Insulin Pricing Scheme;

e. Written communications made by Sanofi, including checks, relating to rebates or other financial inducements paid to each of PBM Defendants to persuade them to advocate Sanofi's diabetes medications;

f. Written and oral communications with U.S. government agencies and payors, such as Plaintiff Harris County, that fraudulently misrepresented what the reported prices were, or that they were intended to deter investigations into the true nature of the reported prices or to forestall changes to reimbursement based on something other than reported prices;

g. Written and oral communications with payors, including Plaintiff Harris County, regarding and/or negotiating the price of diabetes medications;

h. Written and oral communications to Plaintiff Harris County, including marketing and solicitation material sent by each PBM Defendant at least in 2003, 2008 and 2016, as well as annual written reports, regarding the existence, amount, or purpose of payments made by Sanofi to each PBM Defendant for the diabetes medications described herein and the purpose of PBM Defendants' formularies;

i. Transmission of reported prices to third parties, including Plaintiff Harris County;

j. Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities—the wrongful proceeds of the Insulin Pricing Scheme; and

k. In addition to the above-referenced RICO predicate acts, Sanofi's and each PBM Defendant's corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions, in furtherance of the Insulin Pricing Scheme, including within Texas.

D. Conduct of Sanofi-PBM Enterprises' Affairs

543. Sanofi and each PBM Defendant has participated in and exerted control over the Sanofi-PBM Enterprises with which they were associated and, in violation of Section 1962(c) of RICO, Sanofi and each PBM Defendant has conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation was carried out in the following ways:

- a. Sanofi directly controls the secret payments it provides to PBM Defendants for its diabetes medications, which determines the amount of each PBM Defendants' compensation from Sanofi;
- b. PBM Defendants directly control their respective drug formularies, which determines the utilization of Sanofi's diabetes medications;
- c. Sanofi directly controls the prices that it publicly reports;
- d. Sanofi directly controls the creation and distribution of marketing, sales, and other materials used to inform each PBM Defendant of the profit potential from its diabetes medications;
- e. Each PBM Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform payors of the benefits and cost-saving potential of contracting with PBMs;

f. Each PBM Defendant and Sanofi has relied upon its employees and agents to promote the Insulin Pricing Scheme through the U.S. mails, through interstate wire facilities and through direct contacts with providers and payors; and

g. Sanofi has controlled and participated in the affairs of each Sanofi-PBM Enterprises by providing rebates and/or other inducements to place Sanofi's diabetes medications on each PBM Defendant's formularies or advocate the use of certain diabetes medications. These inducements include Sanofi's payment to each PBM Defendant of: (i) access rebates for placement of products on the PBMs' formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) undisclosed administrative fees; and (iv) other fees and grants.

h. Each PBM Defendant has controlled and participated in the affairs of the Sanofi-PBM Enterprise with which it is associated by incentivizing and agreeing with Sanofi to exchange formulary placement for inflated reported prices and payments as described above. Furthermore, PBM Defendants hide the actual amount of secret refund payments received from Sanofi by relabeling them discounts, credits, concession fees, administrative fees, etc. and then not disclosing the amount paid under these labels.

i. Each PBM Defendant did distribute through the U.S. mail and interstate wire facilities, promotional and other materials which claimed that the money paid from Sanofi to each PBM Defendant saved Plaintiff Harris County money on their prescription needs.

j. Sanofi represented to the general public and Harris County—by publishing and promoting reported prices without stating that these reported prices differed substantially from the prices realized by Sanofi and each PBM Defendant—that the reported prices of diabetes medications reflected or approximated the net cost of these drugs and resulted from transparent and competitive market forces.

k. Each of the Sanofi-PBM Enterprises identified above had hierarchical decision-making structure headed by Sanofi and each PBM Defendant.

l. In violation of Section 1962(c) of RICO, Sanofi and each PBM Defendant has conducted the affairs of each of the Sanofi-PBM Enterprises with which they associated in order to carry out the Insulin Pricing Scheme.

E. Defendants’ Pattern of Racketeering Activity

544. Sanofi and each PBM Defendant has conducted and participated in the affairs of their respective Sanofi-PBM Enterprises through a pattern of racketeering activity, including acts that are unlawful under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud.

545. Sanofi’s and each PBM Defendant’s pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of the Insulin Pricing Scheme described above. Each of these fraudulent mailings and interstate wire transmissions constitutes a “racketeering activity” within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a “pattern of racketeering activity,” within the meaning of 18 U.S.C. §

1961(5), in which Sanofi and each PBM Defendant intended to defraud Plaintiff Harris County.

546. By intentionally and artificially inflating the reported prices, by misrepresenting the purpose behind both the payments made from Sanofi to each PBM Defendant and each PBM Defendant's formulary decisions and by subsequently failing to disclose such practices to the public and Harris County, Sanofi and each PBM Defendant engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

547. Sanofi's and each PBM Defendant's racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive Plaintiff Harris County.

548. Each separate use of the U.S. mails and/or interstate wire facilities employed by Sanofi and each PBM Defendant was related, had similar intended purposes, involved similar participants and methods of execution and had the same results affecting the same victims, including Harris County.

549. Sanofi and each PBM Defendant engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the respective Sanofi-PBM Enterprises with which each of them is and was associated in fact.

F. Defendants' Motive

550. Sanofi's and each PBM Defendant's motives in creating and operating the Insulin Pricing Scheme and conducting the affairs of the Sanofi-PBM Enterprises described herein was to fraudulently obtain sales of and profits from diabetes medications.

551. The Insulin Pricing Scheme was designed to, and did, encourage others, including Plaintiff Harris County, to advocate the use of Sanofi's products and to pay for

those diabetes medications based on a fraudulently inflated price. Sanofi used the Insulin Pricing Scheme to obtain formulary placement to sell more of its drugs without having to cut into its profit margin. Each PBM Defendant used the Insulin Pricing Scheme to inflate the price Plaintiff Harris County paid for diabetes medications in order to profit off the Secret Payment Game, the Pharmacy Spread and their profit margins on their mail order pharmacies, as discussed above.

G. Sanofi-PBM Enterprises' Insulin Pricing Scheme Damaged Harris County

552. Each Sanofi-PBM Enterprise's violations of federal law and pattern of racketeering activity has directly and proximately caused Plaintiff Harris County to be injured in its business or property.

553. The price Harris County pays for Lantus, Toujeo, Soliqua and Apidra is directly tied to Sanofi's reported prices.

554. No other intermediary in the supply chain has control over or is responsible for the reported prices on which Harris County's payments are based other than the Sanofi-PBM Defendant Enterprises.

555. PBM Defendants set the price by which Harris County paid for the at issue diabetes medications. PBM Defendants also receive payments made by Harris County for the at issue diabetes medications.

556. During the relevant time period, each PBM Defendant provided PBM services to Plaintiff Harris County.

557. The entire basis behind each Sanofi-PBM Enterprise's fraudulent scheme was to convince Plaintiff Harris County to pay inflated prices for diabetes medications in order to make enormous profits.

558. Each Sanofi-PBM Enterprise controlled and participated in the Insulin Pricing Scheme that was directly responsible for the artificially inflated reported prices upon which the price Plaintiff Harris County paid was based.

559. Thus, Harris County was damaged as a result of the Insulin Pricing Scheme. But for the misrepresentations and inflated prices created by the Insulin Pricing Scheme that each Sanofi-PBM Enterprise employed, Harris County would have paid less for diabetes medications.

560. As explained above, Harris County's damages are the difference between the price that Harris County paid for the at issue drugs and what it would have paid absent the Insulin Pricing Scheme.

561. Harris County was directly harmed by the Insulin Pricing Scheme and is entitled to seek a remedy for the economic harms to Harris County from Defendants' fraudulent scheme.

562. Harris County's damages are separate and distinct from any other victim that was harmed by the Sanofi-PBM Defendant Enterprises' Insulin Pricing Scheme.

563. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Harris County for three times the damages that Harris County has sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

564. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964 of RICO, Plaintiff Harris County seeks injunctive relief against Sanofi and PBM Defendants for their fraudulent reporting of their prices and their continuing acts to affirmatively misrepresent and/or conceal and suppress material facts concerning their artificially inflated prices for diabetes medications, plus the costs of bringing this suit,

including reasonable attorneys' fees. Absent an injunction, the effects of this fraudulent, unfair and unconscionable conduct will continue. Plaintiff Harris County continues to purchase Sanofi's diabetes medications. And Harris County will continue to pay based on the Defendants' fraudulent reported prices. This continuing fraudulent, unfair, and unconscionable conduct is a serious matter that calls for injunctive relief as a remedy. Plaintiff Harris County seeks injunctive relief, including an injunction against Sanofi and PBM Defendants, to prevent them from affirmatively misrepresenting and/or concealing and suppressing material facts concerning their artificially inflated prices for diabetes medications.

FOURTH CAUSE OF ACTION

Violations of RICO, 18 U.S.C. § 1962(d) By Conspiring to Violate 18 U.S.C. § 1962 (c) (Against All Defendants)

565. Plaintiff Harris County re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

566. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

567. Defendants have violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the affairs of the § 1962(c) Manufacturer Defendant-PBM Defendant Insulin Pricing Enterprises described previously through a pattern of racketeering activity.

568. As set forth in detail above, Defendants' co-conspirators each knowingly agreed to facilitate the Insulin Pricing Scheme through their respective RICO enterprises and have engaged in numerous overt and predicate fraudulent racketeering acts in

furtherance of the conspiracy. Specifically, Manufacturer Defendants agreed to and did inflate the reported prices of the at issue drugs to achieve an unlawful purpose and PBM Defendants and Manufacturer Defendants agreed to and did make false or misleading statements or material omissions regarding the negotiations between Defendants, the use and purpose of the secret payments paid to PBM Defendants, the selection of which diabetes medications were granted preferred formulary status and that the reported price was a result of transparent and competitive market forces. The truth about these representations would be material to a reasonable consumer, including Plaintiff Harris County.

569. From the outset, Defendants knew, but did not disclose, that the prices that Defendants reported and published for diabetes medications did not reflect the prices realized by Defendants for those products. Defendants knew that the reported prices they selected were not reasonable approximations of competitive market prices for diabetes medications. Yet they held out these reported prices as reasonable approximations of the cost of diabetes medications and reasonable bases for Plaintiff Harris County to pay for the at issue drugs. Manufacturer Defendants substantially inflated the reported prices of the at issue drugs so they could offer larger spreads to PBM Defendants in exchange for favorable formulary positions. Defendants knew, but did not disclose, that the price spreads did not reduce the prices paid by Harris County who purchased diabetes medications based on reported price. Defendants knowingly and deliberately misled Plaintiff Harris County regarding the pricing of the at issue drugs.

570. The nature of the above-described Defendants' co-conspirators' acts, material misrepresentations and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation

of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

571. Defendants have and continue to engage in the commission of overt acts, including the following unlawful racketeering predicate acts:

- a. Multiple instances of mail fraud in violations of 18 U.S.C. § 1341;
- b. Multiple instances of wire fraud in violations of 18 U.S.C. § 1343; and
- c. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

572. Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and will continue. Harris County has been injured in its property by reason of these violations: Harris County has paid more for the at issue drugs than they would have but for Defendants' conspiracy to violate 18 U.S.C. § 1962(c).

573. Defendants' conspiracy to engage in and overt acts in furtherance of racketeering activity directly and proximately injured Harris County: Harris County substantially overpaid for the at issue drugs when they paid for these medicines based on Defendants' reported prices.

574. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are jointly and severally liable to Harris County for three times the damages Harris County has sustained, plus the cost of this suit, including reasonable attorneys' fees.

FIFTH CAUSE OF ACTION

Texas Deceptive Trades Practices-Consumer Protection Act (Against All Defendants)

575. Plaintiff Harris County re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

576. Plaintiff Harris County brings claims under the Texas Deceptive Trade Practices-Consumer Protection Act. TEX. BUS. & COMM. CODE §§ 17.41–.63 (the “DTPA”). Plaintiff Harris County is a consumer under the DTPA because it is “a subdivision . . . of this state who seeks or acquires by purchase or lease, any goods or services,” including diabetes medications and pharmacy benefit management services. TEX. BUS. & COMM. CODE § 17.45(4).

577. Plaintiff alleges that all conditions precedent to filing this DTPA claim have been performed or have occurred, including all pre-suit notices required under Sections 17.48(b) and 17.505(a) of the DTPA.

578. At all times, Defendants and their agents have engaged in conduct constituting “trade” and “commerce,” as defined in § 17.45(6) of the DTPA.

579. Defendants committed false, misleading or deceptive acts or practices that Plaintiff Harris County relied on, including:

a. “[R]epresenting that goods or services have . . . characteristics . . . which they do not have . . .” TEX. BUS. & COM. CODE § 17.46(B)(5); *see also* TEX. BUS. & COM. CODE § 17.50(A)(1)(A).

- In particular, by publishing reported prices for diabetes medications knowing that payors, like Harris County, pay for these medications based on such prices, Defendants falsely represented that their diabetes medications have characteristics which they do not have—that their reported prices are accurate, bear a reasonable relationship to the net prices realized by Defendants and result from transparent and competitive market forces. *See* ¶¶ 180-185, 187-193, 202-08.

- In furtherance of Defendants' fraudulent conspiracy, at least once a year for each year during the relevant time period Defendants reported and published false prices for each at-issue drug. *See* Appendix B for a representative sample from 2013-2019 of Defendants' false reported prices for the at-issue drugs and the date upon which Harris County paid for units based on each false inflated price during that time. To note, Appendix B only provides for 2013-2019, which is a subset of the damages period alleged in this Complaint which includes 2003-present.
- In addition, PBM Defendants know that payors, including Harris County, rely on PBMs to achieve the lowest possible drug prices, including for the at-issue diabetes medications. By basing the price on Manufacturer Defendants' reported price, upon which payors, including Harris County, pay for diabetes medications, PBM Defendants knowingly reinforced the Manufacturers' false and inflated price misrepresentations and ensured that these representations would harm Harris County. *See* ¶¶ 202-08, 297-302.
- These representations are false and at all relevant times Defendants knew they were false. Defendants knew that Manufacturers' reported prices do not result from competitive market forces, but rather are artificially inflated in coordination with their competitors and with PBM

Defendants for the purpose of maximizing profits. At all times relevant hereto, Defendants affirmatively withheld this truth from Harris County even though Defendants knew that Harris County's intention was to pay the lowest possible price for diabetes medications and Harris County's expectation was to pay a price that resulted from competitive market forces. *See* ¶¶ 234-269, 276-291, 331-335.

b. “[M]aking false or misleading statements of fact concerning the reasons for, existence of, or amount of price reductions.” TEX. BUS. & COM. CODE § 17.46(B)(11); *see also* TEX. BUS. & COM. CODE § 17.50(A)(1)(A).

- In particular, at all relevant times, PBM Defendants made false and misleading statements concerning the reasons for, existence of, and amount of price reductions by misrepresenting to payors, including Harris County, that the money that PBM Defendants receive from the Manufacturer Defendants lowers the overall price of diabetes medications; that PBM Defendants are transparent with payors, including Harris County, regarding these payments; and, that these payments did, in fact, save payors, including Harris County, money on diabetes medications. *See also supra* ¶¶ 218, 304-330.
- At all times relevant hereto, these representations were false and Defendants knew they were false when they made them. PBM Defendants knew they were not transparent with payors,

including Harris County, regarding the payments PBM Defendants required and received from Manufacturer Defendants. At all relevant times PBM Defendants concealed these payments in order to hide the significant revenue they generated for PBM Defendants. PBM Defendants also knew, at all times relevant hereto, that the payments received from Manufacturers were not reducing the overall price of diabetes medications, but rather were an integral part of the collaborative scheme that was artificially inflating the price of diabetes medications. *See* ¶¶ 234-257, 276-91, 331-341.

c. “[F]ailing to disclose information concerning goods or services which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed.” TEX. BUS. & COM. CODE § 17.46(B)(24); *see also* TEX. BUS. & COM. CODE § 17.50(A)(1)(A).

- At all times relevant hereto, Manufacturer Defendants failed to disclose that their reported prices for their diabetes medications did not result from competitive market forces, but rather were artificially inflated in coordination with their competitors and with PBM Defendants for the purpose of maximizing profits. *See* ¶¶ 234-257.
- At all times relevant hereto, PBM Defendants failed to disclose that their formulary construction and the payments that they

receive from Manufacturer Defendants did not benefit payors, including Harris County, and did not lower the overall price for diabetes medications, as PBM Defendants represent that they do. *See also supra* ¶¶ 331-341.

- Defendants failed to disclose this information to induce payors, including Harris County, to pay for diabetes medications at artificially and egregiously inflated prices. If Defendants had disclosed the fact that their fraudulent scheme had artificially and egregiously inflated the price of the at-issue diabetes medication to payors, including Harris County, Harris County would not have been willing to pay for diabetes medications at these inflated prices.

580. Defendants also committed unconscionable actions. TEX. BUS. & COM. CODE § 17.50(A)(3).

a. In particular, Defendants' conduct, to Harris County's detriment, took advantage of Harris County's lack of knowledge of their pernicious scheme to a grossly unfair degree. TEX. BUS. & COM. CODE § 17.45(5). Defendants have never disclosed the details of their agreements or the payments that Manufacturer Defendants pay PBM Defendants related to each at-issue drug. *See* ¶¶ 331-341. Further, PBM Defendants do not disclose the details of their agreements with pharmacies related to the amount they pay pharmacies for each at-issue drug sold. *See also supra* ¶¶ 215-16, 336-341.

b. Plaintiff Harris County had no way of discerning that Defendants were, in fact, deceiving it because Defendants possessed exclusive knowledge

regarding the nature of their pricing of diabetes medications; intentionally concealed the foregoing from Plaintiff Harris County; and made purposefully incomplete or false representations about the pricing of diabetes medications and the Defendants' fraudulent scheme that directly affected pricing, while purposefully withholding material facts from Plaintiff Harris County that contradicted these representations. Defendants' actions, representations and misrepresentations demonstrate callous disregard for not only the rule of law but also public health and the public fisc.

c. As a direct result of Harris County's lack of knowledge regarding Defendants' misrepresentations—a lack of knowledge caused by Defendants themselves—Harris County paid for the at-issue diabetes medications at egregiously inflated prices.

581. Defendants' violations of the DTPA were a producing cause of Plaintiff Harris County's damages, TEX. BUS. & COM. CODE § 17.50(a). Each purchase Harris County made based on the false and inflated prices generated by the unlawful scheme described herein represents an independent harm to the County flowing directly from Defendants' conspiracy.

582. As a direct and proximate result of Defendants' fraudulent Insulin Pricing Scheme, Harris County sustained damages, including but not limited to paying excessive and inflated prices for diabetes medications described herein every time it paid for an at issue drug.

583. Defendants engaged in a conspiracy to violate the DTPA. *See Four Bros. Boat Works, Inc. v. Tesoro Petroleum Companies, Inc.*, 217 S.W.3d 653, 667 (Tex. App.—

Houston [14th Dist.] 2006, pet. denied) (“Two or more persons can be held liable for a conspiracy to violate the DTPA.”).

a. In particular, each of the PBM and Manufacturer Defendants agreed to and carried out acts in furtherance of the Insulin Pricing Scheme that artificially and egregiously inflated the price of diabetes medications for payors, including Harris County.

b. Defendants’ conduct described herein constitutes a conspiracy. Defendants have aided and abetted each other to violate the Texas Deceptive Trade Practices Act. Defendants are all jointly and severally liable for the actions taken in furtherance of their joint conduct.

c. Each Defendant had a conscious commitment to participate in the Insulin Pricing Scheme. As detailed in paragraphs 258-269, Defendants explicitly admitted that they agreed to and did participate in the Insulin Pricing Scheme.

d. As detailed in paragraphs 180-185, 187-193 and 202, Manufacturer Defendants’ agreed with each other to increase, in lockstep, the reported price of their diabetes medications in order to participate in the Insulin Pricing Scheme.

e. This agreement between Manufacturer Defendants was necessary because their diabetes medications have similar efficacy and risk profiles and thus purchasers choose whose product to buy based primarily on price. In a competitive market such as this one unilateral price increases would result in loss of market share and removal from preferred positions on PBM Defendants’ formularies. Thus, it would have been economically irrational for any one Manufacturer Defendant to raise its prices without assurance that its competitors would also

increase prices and assurance from PBM Defendants that it would receive preferred formulary positions in exchange for these inflated prices.

f. As detailed paragraphs 234-257, Manufacturer Defendants agreed with PBM Defendants to intentionally and artificially raise their reported diabetes medication prices and then pay back a significant portion of those prices to PBM Defendants.

g. As detailed paragraphs 234-257, in exchange for Manufacturer Defendants' inflating their prices and making large secret payments, PBM Defendants agreed to and did grant preferred formulary status to Manufacturer Defendants' diabetes medications.

h. In a competitive PBM market, PBM Defendants would have granted formulary position based on lower reported prices, rather than inflated prices and secret payments.

i. In a competitive market, the non-transparent and convoluted secret payment system devised by Defendants would have been unnecessary.

j. In a competitive market, if a PBM Defendant acted unilaterally to grant formulary position based upon higher reported prices and non-transparent payments, the services and formularies that PBM made available to payors, such as Harris County, would be less competitive compared to those of ostensibly competing PBMs granting formulary position on lower, transparent prices.

k. Each Defendant shares a common purpose of perpetuating the Insulin Pricing Scheme and neither PBM Defendants nor Manufacturer Defendants alone could have accomplished the Insulin Pricing Scheme without their co-conspirators.

l. PBM Defendants need Manufacturer Defendants to artificially inflate the reported price of their diabetes medications and to make secret payments back to PBM Defendants in order for PBM Defendants to profit off the Insulin Pricing Scheme.

m. Manufacturer Defendants need PBM Defendants to grant their diabetes medications preferred formulary placement and to convince payors, such as Harris County, to pay for such drugs based on the inflated reported prices.

n. In furtherance of the Insulin Pricing Scheme, PBM Defendants and Manufacturer Defendants made joint decisions, were in regular communication, and met on a regular basis regarding artificially inflating the reported price of diabetes medications and the regular flow of payments from Manufacturer Defendants to PBM Defendants for formulary placement including: (i) access rebates for placement of products on their formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) undisclosed administrative fees; and (iv) other fees and grants in an effort to promote products.

o. In addition to the preceding direct evidence of an agreement, Defendants' agreement and conscious commitment to the Insulin Pricing Scheme is also demonstrated by:

- As detailed in paragraphs 228-232, Defendants frequently engaged in private communications and meetings at annual conferences, industry trade associations and through private online forums;
- As detailed in paragraphs 336-341, Defendants refuse to disclose the details of their pricing structures, agreements and

sales figures in order maintain the secrecy of the Insulin Pricing Scheme;

- Numerous ongoing government investigations, hearings and inquiries targeting the Insulin Pricing Scheme and the collusion and anticompetitive behavior of Defendants, including:
 - In 2016, Manufacturer Defendants received civil investigative demands from the State of Washington and the State of New Mexico relating to the pricing of their insulin products and their relationships with PBM Defendants;
 - In 2017, Manufacturer Defendants received civil investigation demands from the States of Minnesota, California and Florida related to the pricing of their insulin products;
 - Letters from numerous senators and representatives in recent years, including Senator Bernie Sanders (D-VT), Representative Elijah Cummings (D-MD), and Representative Tim Burchett (TN-02) to the Justice Department and the Federal Trade Commission asking them to investigate potential collusion and anticompetitive behavior among Defendants;
 - A 2017 House Oversight committee investigation into the corporate strategies of drug companies, including Manufacturer Defendants, seeking information on the increasing price of drugs and manufacturers efforts to preserve market share and pricing power;
 - A 2018 report issued by Tom Reed (R-NY) and Diana DeGette (D-CO) titled “Insulin: A Lifesaving Drug Too Often Out Of Reach” aimed addressing the dramatic increase in the price of insulin; and
 - Several 2019 hearings before both the Senate Financing Committee and the House Oversight and Reform Committees on the Insulin Pricing Scheme;

- Recent threats by the U.S. Congress and State Legislatures to subpoena Defendants for documents related to insulin pricing because of Defendants' failures to comply with federal and state investigations.
- The fact that the astronomical rise in the price of the at-issue drugs coincides with PBM Defendants' rise to power within the pharmaceutical pricing system starting in 2003.

584. Each at-issue purchase Harris County made for diabetes medications at Defendants' artificially inflated prices, which was a direct result of Defendants' misrepresentations, constitutes a separate violation of the Texas DTPA.

a. Each purchase that Harris County made for the at-issue drugs during the relevant time period represents a discrete event. There are 60 different National Drug Codes (NDCs)¹⁰⁸ associated with the at-issue diabetic medications; these various medications are made by three different manufacturers, the purchases took place at varying times and the purchases paid for by Harris County were dispensed at countless different pharmacies—including the PBMs' mail order pharmacies—as well as were delivered directly to Harris County jails. Each purchase made by Harris County was based on the inflated published price for the relevant NDC at the precise time of the purchase. *See* Appendix B.

- None of these transactions ever equaled or exceeded \$100,000 and during the relevant time period Harris County, as a payor, has never paid for diabetes medications (or pharmaceutical drugs in general) in an aggregate amount or for a contracted

¹⁰⁸ Every drug, dosage and package size/type has an independent NDC.

price that equaled or exceeded \$100,000. Rather, Harris County, as a payor, has at all times during the relevant period paid for the at-issue drugs based on a per-prescription price that is set in relation to the Manufacturer Defendants' reported prices.

b. Each of these discrete purchases was made at a price that was inflated as a direct result of Defendants' conspiracy and was paid by Harris County because of its reliance on Defendants' misrepresentations discussed above in paragraphs 579 and 580. Thus, each discrete purchase constitutes a separate violation of the DTPA. TEX. BUS. & COM. CODE § 17.46(B)(5); TEX. BUS. & COM. CODE § 17.46(B)(11); TEX. BUS. & COM. CODE § 17.46(B)(24); TEX. BUS. & COM. CODE § 17.45(5); TEX. BUS. & COM. CODE § 17.50(A)(1)(A).

c. Further, each of these discrete purchases directly benefitted Harris County as the health and well-being of its employees is essential to Harris County's ability to fulfill its mission as a local governmental entity providing essential services to millions of taxpayers.

585. Plaintiff Harris County's economic damages include but are not limited to its out-of-pocket losses and benefit-of-the-bargain damages. TEX. BUS. & COM. CODE § 17.50(b)(1); *Brown & Brown of Texas, Inc. v. Omni Metals, Inc.*, 317 S.W.3d 361, 387 (Tex. App.—Houston [1st Dist.] 2010, pet. denied) ("The plaintiff may recover either 'the value of that which he has received' ('out of pocket' damages) or 'the difference between the value as represented and the actual value received' ('benefit of the bargain' damages)").

586. Because Defendants' actions were committed intentionally or knowingly, Plaintiff Harris County is entitled to recover up to three times the amount of its economic damages. TEX. BUS. & COM. CODE § 17.50(b)(1).

587. Plaintiff Harris County seeks injunctive relief under TEX. BUS. & COM. CODE § 17.50(b)(2) because Defendants' conduct is a producing and ongoing cause of damage to Plaintiff Harris County, as well as all diabetic consumers in Texas. Plaintiff Harris County continues to pay for the at-issue diabetes medications at artificially inflated prices because of Defendants' fraudulent scheme.

588. Plaintiff Harris County seeks costs and attorneys' fees under the DTPA. TEX. BUS. & COM. CODE § 17.50(d).

SIXTH CAUSE OF ACTION

Common Law Fraud (Against All Defendants)

589. Plaintiff Harris County re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

590. As discussed in detail in paragraphs 304-347, Defendants made numerous false representations to Harris County, that Defendants knew were false, with the intent to induce Harris County into selecting their formularies and purchasing the at issue diabetes medications at artificially inflated prices and Harris County relied on these false representations in selecting PBM Defendants' formularies and purchasing millions of dollars of the at issue drugs at artificially inflated prices to its significant detriment.

591. At all times during the relevant period, Defendants affirmatively and intentionally misrepresented and/or concealed and suppressed material facts concerning: (a) that PBM Defendants negotiate with Manufacturer Defendants for the benefit of Harris

County and to save Harris County money; (b) that PBM Defendants use their market power to maximize savings for Harris County; (c) that PBM Defendants design pharmacy plans and construct formularies for the purposes of promoting health and safety; (d) that PBM Defendants are transparent with payors, including Harris County, regarding the payments they receive from Manufacturer Defendants and (e) that Manufacturer Defendants reported drug prices bear a reasonable relationship to the net price realized by Defendants and result from competitive market forces.

592. Defendants knew that the representations described above were false when they made the representations—the secret payments and formulary positions agreed upon between Defendants did not promote the health and safety of Harris County’s Beneficiaries and did not lower the price Harris County paid for the at issue diabetes medications, but rather were primary factors driving the exponential increase in the amount that Harris County paid for these drugs.

593. Defendants made these false representations directly and indirectly to Harris County through marketing materials and presentations, as well as by publishing their inflated reported prices and utilizing the reported prices to set the price Harris County paid for diabetes medications. Defendants also made these representations in public statements and testimonies in the media, on various websites, in Defendants’ governmental filings and at Congressional hearings.

594. Defendants made these representations for the sole purpose of inducing reliance by Harris County into selecting PBM Defendants formularies and purchasing diabetes medications at artificially inflated prices.

595. Defendants’ false representations and omissions were material to Plaintiff Harris County.

596. Plaintiff Harris County reasonably relied on Defendants' deception in paying for diabetes medications at inflated prices. Plaintiff Harris County had no way of discerning that Defendants were, in fact, deceiving it because Defendants possessed exclusive knowledge regarding the nature of the pricing of diabetes medications; intentionally concealed the foregoing from Plaintiff Harris County; and made incomplete or negligent representations about the pricing of the diabetes medications and the Defendants' role in that pricing, while purposefully withholding material facts from Plaintiff Harris County that contradicted these representations.

597. Defendants' actions, representations and misrepresentations demonstrate callous disregard for not only the rule of law but also public health.

598. As a direct and proximate result of Defendants' fraudulent Insulin Pricing Scheme, Harris County sustained damages, including but not limited to paying excessive and inflated prices for diabetes medications described herein.

599. Defendants are liable to Plaintiff Harris County for damages in an amount to be proven at trial. Moreover, because Defendants acted wantonly, maliciously, recklessly, deliberately and with intent to defraud Plaintiff Harris County for the purpose of enriching themselves at Plaintiff's detriment, Defendants' conduct warrants substantial punitive and exemplary damages in an amount to be determined at trial.

SEVENTH CAUSE OF ACTION

Money Had and Received (Against All Defendants)

600. Plaintiff re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

601. Defendants have benefitted from and hold money for selling, setting prices for and negotiating payments for diabetes medications marketed and sold at an artificially inflated price.

602. PBM Defendants have received and retained money and unjust benefits from Plaintiff Harris County in the form of excess payments paid by Plaintiff Harris County to PBM Defendants for diabetes medications. PBM Defendants also have received and retained the proceeds from the Pharmacy Spread discussed above. In addition, PBM Defendants have received and retained secret payments paid by Manufacturer Defendants to PBM Defendants to which Plaintiff Harris County is entitled.

603. Manufacturer Defendants have received and retained money and unjust benefits using the artificially inflated reported prices paid by Harris County to incentivize Manufacturer Defendants into giving their diabetes medications preferred formulary placement. This fraudulent scheme also allowed Manufacturer Defendants to increase the amount of refund payments that they paid to PBM Defendants in exchange for preferred formulary placement without having to compromise their own profit margins.

604. As a result of Defendants' Insulin Pricing Scheme, inequity has resulted and it would be unconscionable for Defendants to retain these monies and benefits.

605. Because Defendants concealed their fraud and deception, Plaintiff Harris County was not aware of the true facts concerning the Insulin Pricing Scheme described herein and did not benefit from Defendants' misconduct.

606. Defendants knowingly accepted the money and unjust benefits of its fraudulent conduct.

607. As a result of Defendants' misconduct, an amount of money and Defendants' unjust enrichment should be disgorged and returned to Plaintiff Harris County in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION

Unjust Enrichment (Against All Defendants)

608. Plaintiff re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

609. Defendants have benefitted from the Insulin Pricing Schemes by selling, setting prices for and negotiating discounts for diabetes medications marketed and sold at an artificially inflated price.

610. Defendants wrongfully secured and retained unjust benefits from the Plaintiff Harris County, in the form of amounts paid for diabetes medications based on fraudulently inflated prices and in the form of secret payments made by Manufacturer Defendants to PBM Defendants and inequity has resulted.

611. It is inequitable and unconscionable for Defendants to retain these benefits.

612. Defendants knowingly accepted the unjust benefits of its fraudulent conduct.

613. As a result of Defendants' misconduct, the amount of their unjust enrichment should be disgorged and returned to Plaintiff Harris County, in an amount to be proven at trial.

NINTH CAUSE OF ACTION

Civil Conspiracy (Against All Defendants)

614. Plaintiff re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

615. Defendants' conduct described herein constitutes a civil conspiracy and aiding and abetting each other to violate federal law, the Texas Deceptive Trade Practices Act and to commit the torts of fraud, unjust enrichment and money had and received. In furtherance of their conspiracy, Defendants have undertaken efforts to eliminate competition in the insulin market. As a direct result of the overt acts taken in furtherance of Defendants' conspiracy, Harris County has suffered damages in an amount to be proven at trial. Defendants are all jointly and severally liable for the actions taken in furtherance of their joint conduct.

VII. APPLICATION FOR TEMPORARY AND PERMANENT INJUNCTION

616. Plaintiff re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

617. After Defendants have been cited to appear and answer, Plaintiff requests the Court to enter a temporary injunction pursuant to the Texas DTPA, TEX. BUS. & COM. CODE §17.50(B)(2), to enjoin Defendants, their agents, employees, and attorneys, together with all persons in concert with them, from engaging in unlawful conduct in violation of the DTPA.

618. Plaintiff further requests that, following a trial on the merits in this case, the Court enter a permanent injunction enjoining Defendants from their unlawful conduct

pursuant to RICO, 18 U.S.C. § 1964, the Sherman Act, 15 U.S. Code § 26, TFEAA, TEX. BUS. & COM. CODE § 15.21(B) and the Texas DTPA, TEX. BUS. & COM. CODE §17.50(B)(2).

VIII. CONDITIONS PRECEDENT

All conditions precedent have been performed, have occurred or have been excused.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff Harris County respectfully prays:

- A. That this Court enter judgments against Defendants and in favor of Plaintiff Harris County for violations of federal and state laws and legal standards invoked herein;
- B. That this Court award Plaintiff Harris County monetary relief, including damages, restitution, disgorgement and/or all other available legal and equitable monetary remedies available under the federal and state laws set forth in this Complaint and the general equitable powers of this Court, to be trebled with interest and all exemplary and/or punitive damages that may be awarded, as necessary to remedy the harm from Defendants' acts described in this Complaint; and
- C. That this Court issue a preliminary and permanent injunction enjoining Defendants from continuing to engage in their unlawful conduct.
- D. Plaintiff further prays that Plaintiff recover its attorneys' fees, all costs of suit, prejudgment and post judgment interest and for such other and further relief to which Plaintiff may show itself entitled at law or equity.

X. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs respectfully demand a trial by jury on all issues so triable.

Dated: October 13, 2020

Respectfully submitted,

**OFFICE OF HARRIS COUNTY
ATTORNEY, VINCE RYAN**

/s/ Vince Ryan

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CERTIFICATE OF SERVICE

I hereby certify that on October 13, 2020, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the attorneys of record at their e-mail addresses on file with the Court.

/s/ Josh Wackerly
Josh Wackerly